Operation (OPE)

• Main page • Primary tabs • Secondary commands •
• State of the analyzer • Controls • Services •
• R E A G E N T S • M O N I T O R • S A M P L E S •
• W O R K L I S T • M E T H O D S • Work modules •

Complete descriptions of the working parameters required for a routine testing session.

prepared by

Edif
INSTRUMENTS

This manual has been the collaborative action of all the Edif Instruments staff.

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Power-off / Shut-down / Switch-off OPE.48

The Edif line of analyzers features an innovative software based on the minimal number of operational commands needed to accommodate in-depth and comprehensive testing with maximum efficiency. It can be employed immediately by laboratory technicians at all levels of proficiency ... from the beginner on.

The manual begins with a brief but complete overview of the entire work process (OPE.4 to 13) followed by descriptions of the five "Primary tabs" (OPE.14 to 37) which include a complete step-by-step explanation of the entire hierarchy of testing actions and, finally, a discussion of the "Work modules" covering the use of special management features (OPE.38 to 47).

Readers are urged to "Switch-on" (OPE.3) and experiment while following these instructions page by page.

Switch-on / Log-in / Start-up

1 To begin **opening** procedures
switch on the analyzer.
Instrument warm-up will begin (see also OPE.10).

Switch for reagent refrigeration plate

Main power switch

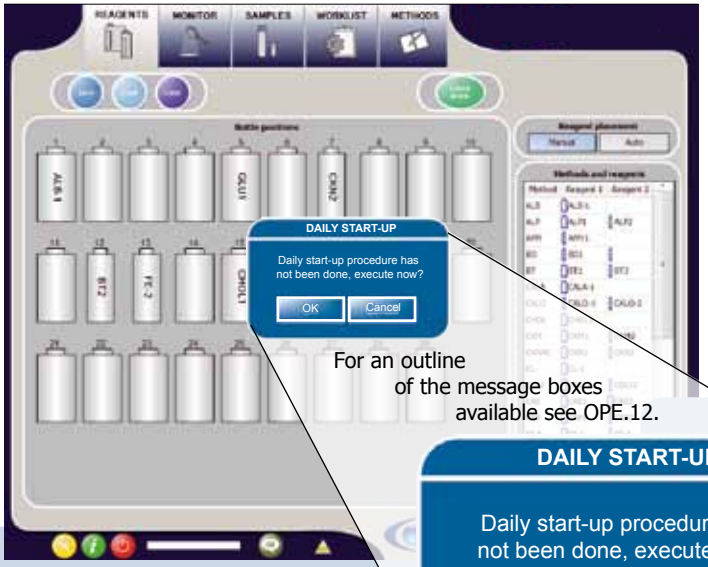
2 Switch on the **PC**
and the **touch screen monitor**.

3 Click on the **HI** icon
to access the **"Log-in"** window.

Enter the appropriate name and password and press OK

Touch screen keyboard provided

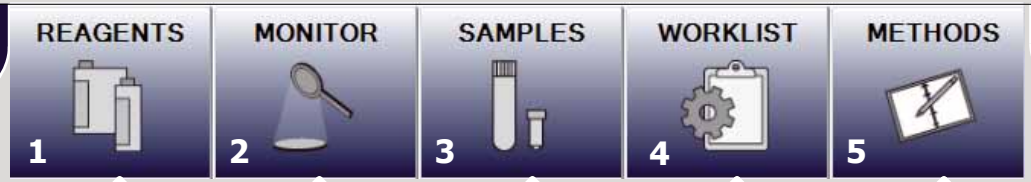
4 Upon entry and confirmation
of the appropriate name and password
the **REAGENTS tab** will appear (see also OPE.14).



For an outline of the message boxes available see OPE.12.

Reminder ...

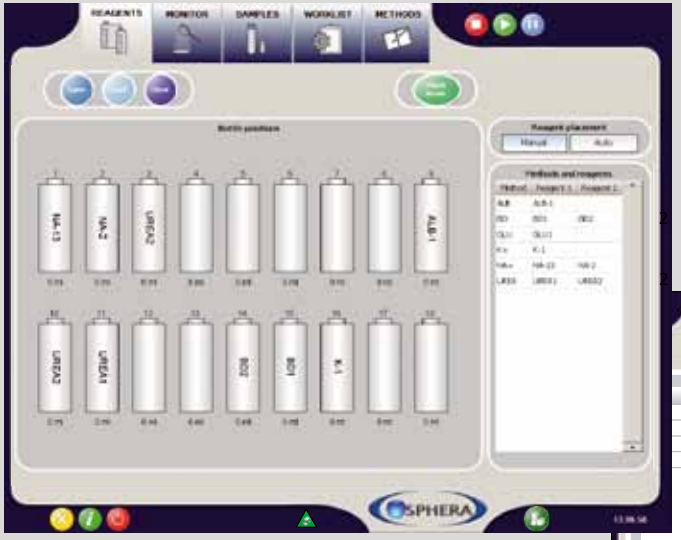
If start-up has not been executed within the last 24 hours, the DAILY START-UP message box will appear. If tests are scheduled to be run, press OK to activate this procedure. Then, upon completion of warm-up, a prime of the hydraulic system, a wash cycle and optical calibration will be executed, and test execution can begin.



Main page

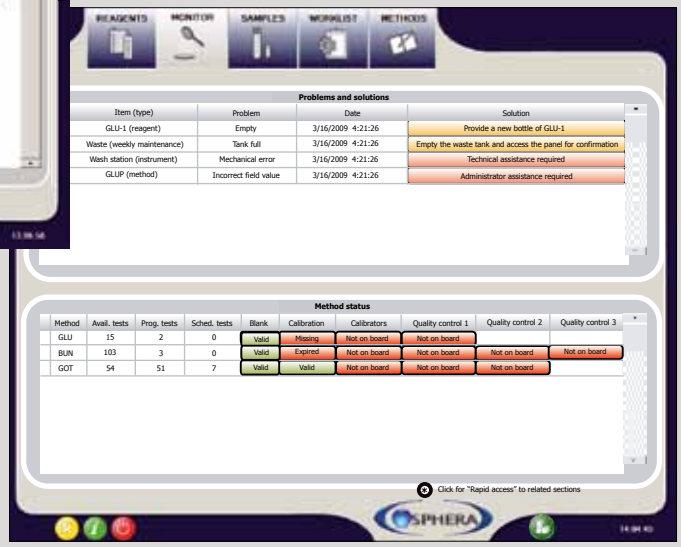
Primary tabs

Reagents tab



**With only "two clicks"
the user is into the very heart
of the testing process giving
immediate access to all working functions
at any time during laboratory routine work.**

Monitor tab


Problems and solutions
Item (type) | Problem | Date | Solution
GLU-1 (reagent) | Empty | 3/16/2009 4:21:26 | Provide a new bottle of GLU-1
Waste (weekly maintenance) | Tank full | 3/16/2009 4:21:26 | Empty the waste tank and access the panel for confirmation
Wash station (instrument) | Mechanical error | 3/16/2009 4:21:26 | Technical assistance required
GLUP (method) | Incorrect field value | 3/16/2009 4:21:26 | Administrator assistance required
Method status
Method | Avail. tests | Prog. tests | Sched. tests | Blank | Calibration | Calibrators | Quality control 1 | Quality control 2 | Quality control 3
GLU | 15 | 2 | 0 | Valid | Missing | Not on board | Not on board
BUN | 103 | 3 | 0 | Valid | Expired | Not on board | Not on board | Not on board | Not on board
GOT | 54 | 51 | 7 | Valid | Valid | Not on board | Not on board | Not on board
Click for "Rapid access" to related sections

1 REAGENTS

• Assign and adjust bottle positions •
• Manage listings •
• Check liquid levels •

2 MONITOR

• Identify and manage problems •
• Provide solutions for problems identified •
• Review method status •

Samples tab

3 SAMPLES

• Manage samples, calibrators and controls •
• Monitor sample tray •
• Sample inspection •
• Request and print reports •

Worklist tab

4 WORKLIST

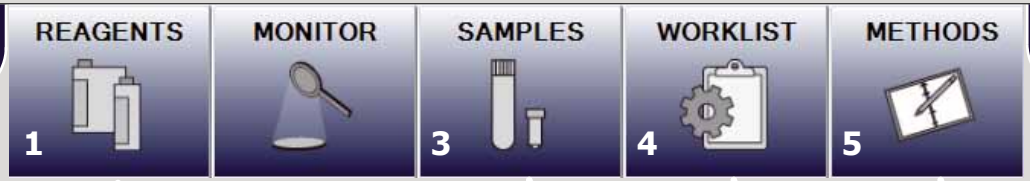
• Create and manage test lists organized in sheets by groups •
• Run, zoom, rerun tests •

Methods tab

5 METHODS

• Set and monitor calibrations •
• Assign quality controls (QC) •
• Access QC results •

human interface by Edif Instruments



Main page, continued

Secondary commands

This level of the command structure is the link to the core functions that give access to the range of testing options provided with this analyzer.

1 REAGENTS tab (REA)

Save assigned positions and file bottle panel for reuse
Retrieve and load a bottle panel from saved file
Clear displayed bottle positions

Employed to check reagent liquid levels when the analyzer is STOPPED (see OPE.17 for complete information).

3 SAMPLES tab (SAM)

Save and file a sample list for reuse (without related tests)
Retrieve and load a sample list from saved file (without related tests)
Clear displayed sample list (with related tests)

Execute a complete scan of "sample barcodes"

Display work form showing tray positions for samples, calibrators and controls

Display work form for sample report
Display work form for sample inspection

Add / Remove a sample
Apply modified data to selected sample

4 WORKLIST tab (WOL)

Save and file all worksheets for reuse (with related samples)
Retrieve and load worksheets from saved file (with related samples)
Clear all worksheets (without related samples)

Create a new worksheet
Remove worksheet selected

Run all tests of the worksheet selected
Print a report of the worksheet selected

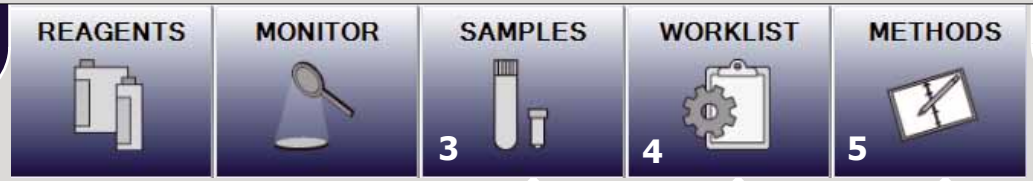
Before continuing users are urged to experiment with the main page command structure. Using the graphics on these two pages as a guide, access each of the numbered tabs above several times and run through the secondary commands at random. A bit of practice early on will ensure a more complete understanding of how to operate this instrument and illustrate just how user friendly it is.

5 METHODS tab (MET)

Access method fields work form
to check the working parameters
of the analysis that can be performed

Access quality control work module
to assign controls to each method,
and check QC results

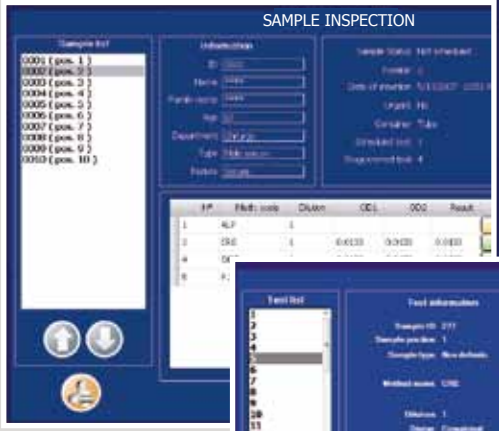
A touch-screen
"Keyboard"
is displayed
where required



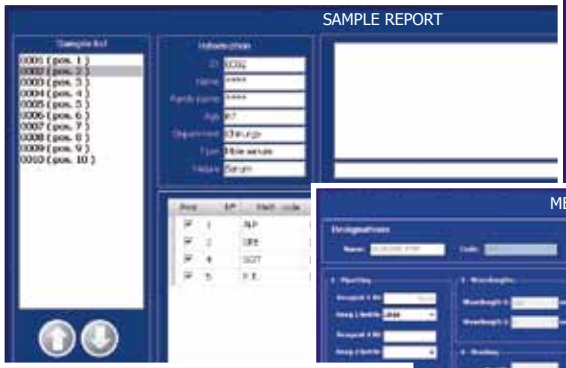
Main page, continued

Work forms

Sample inspection (OPE.23)

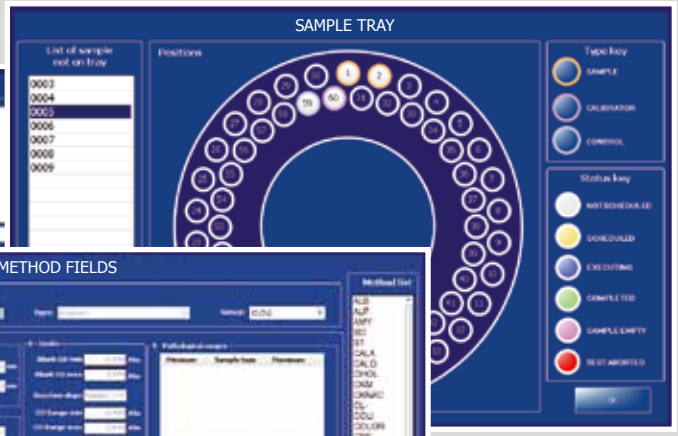


Sample report (OPE.24)



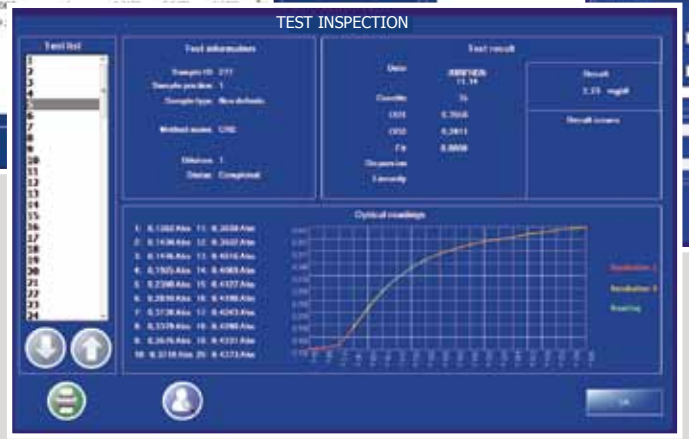
Sample tray

Sample tray (OPE.25)



Fields

Method fields (OPE.36)

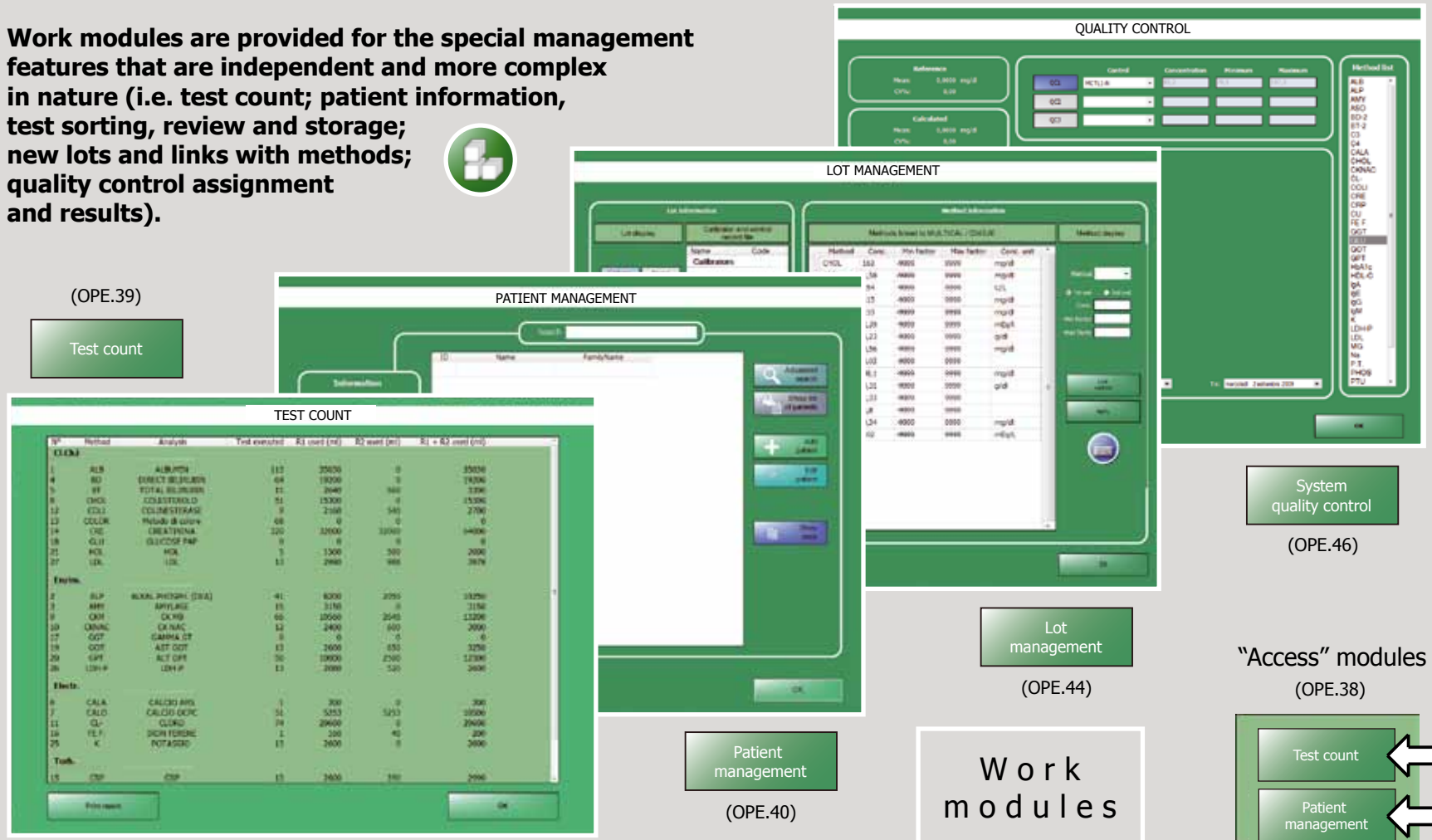


Inspect test

Test inspection (OPE.30)

Work forms are provided for specific functions where access to more detailed information is required to complete operational tasks (e.g. sample lists and status, test lists and results).

Work modules are provided for the special management features that are independent and more complex in nature (i.e. test count; patient information, test sorting, review and storage; new lots and links with methods; quality control assignment and results).



(OPE.39)

Test count

System quality control

(OPE.46)

Lot management

(OPE.44)

Patient management

(OPE.40)

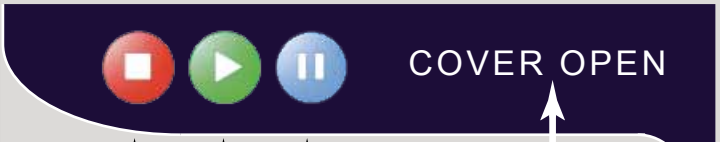
Work modules

"Access" modules

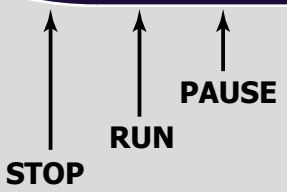
(OPE.38)

- Test count
- Patient management
- Lot management
- System quality control

The state of the analyzer can be monitored or controlled using the icons in the upper right corner of the main page. Icons for additional services and information can be found at the bottom of the main page (OPE.11).



Principal controls of Sphera



State of the analyzer

WARM-UP
Approximately 20 to 30 minutes of warm-up time are required before testing is possible (warm-up status bar shown in lower left panel). When warm-up has finished the analyzer automatically reaches the STOPPED state.

STOPPED
Analyzer is completely stopped. There are no mechanical movements. Testing temperature is maintained.

START-UP
Upon start-up the analyzer begins by executing a prime of the hydraulic system, a wash cycle and the optical calibration of the reaction cells.

CHECKING LEVELS
Indicates that reagent liquid levels are being monitored after a request while in STOPPED state.

RUNNING
The analyzer is running. The reagent-sampling arm is in motion. Tests, problems and liquid levels are constantly being monitored.

COVER OPEN
If the cover is opened during the running state, the analyzer will suspend the sampling of new tests. Dispensations will be skipped until the cover is closed and all tests requiring a second dispensation will be aborted. (Tests requiring no dispensations will continue.)

PAUSE REQUESTED / PAUSED
A pause may be requested at any time and reached (PAUSED) when the current sampling runs have been completed. The instrument cover can then be opened to permit the user to perform on-board functions. (Reagents and samples on board can be removed or added during which time the reading process continues.)

PROBLEM
Indicates that the analyzer has stopped and testing can not continue without user (or technical) intervention.

SHUT-DOWN
The analyzer begins closing procedures by executing the necessary wash cycles. When these are completed the instrument can be switched off (OPE.48).

Daily maintenance
Two procedures should be executed each day.
1) *Start-up.* Recommended daily to ensure that calibration of the optical group is renewed. 2) *Shut-down.* Required to initiate the cleaning of the reaction cells before switching off the analyzer (but only if tests have been executed).

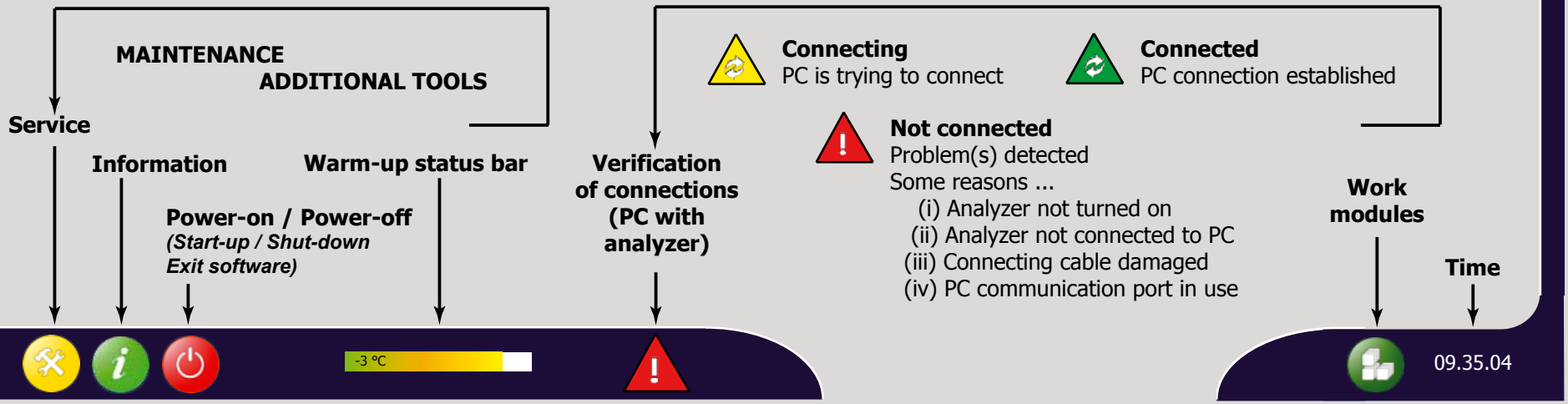
Weekly maintenance
Four procedures are recommended once each week.
1) *Empty waste tank*. 2) *Fill common resource tanks (water / cleaning solution).* 3) *Prime hydraulic system* (this is to ensure the removal of any air trapped in the tubing).

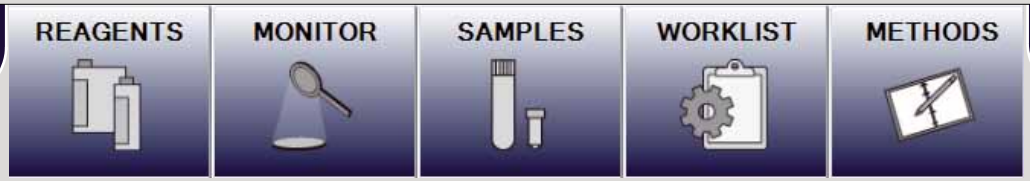
Monthly maintenance
Three procedures should be executed monthly to avoid a shift of test results or the deterioration of critical parts. Listed are ... 1) *Sampling needle rinse*. 2) *Special cuvette wash.* 3) *Testing pumps*. (Note: It is advised that instrument performance tests be run during the course of each month to monitor possible problem development.)

Special maintenance
An occasional procedure should be executed to monitor the remaining life of certain parts. Listed are ...
1) *Reaction cuvettes.* 2) *Pumps.* 3) *Halogen lamp.*
4) *Filters.* 5) *Sampling needle.*

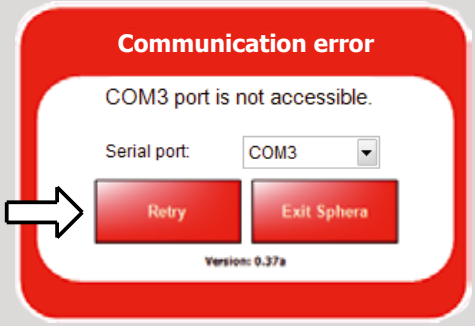
Additional tools
Procedures possible to help save time during testing.
This includes the use of the *manual dilution tool* (for preparing a sample dilution to be added to the test mix as a supplement to normally scheduled dilutions).

Principal services



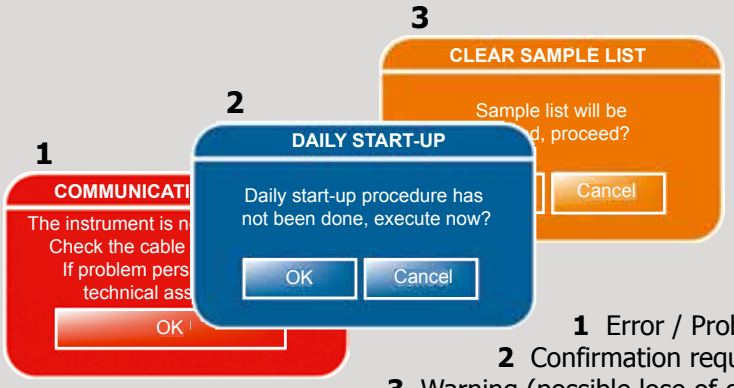


If the PC and the analyzer are "Not connected" for any reason (see OPE.11) the "Communication error" box shown below will be displayed. Check the communcation cable and press "Retry".

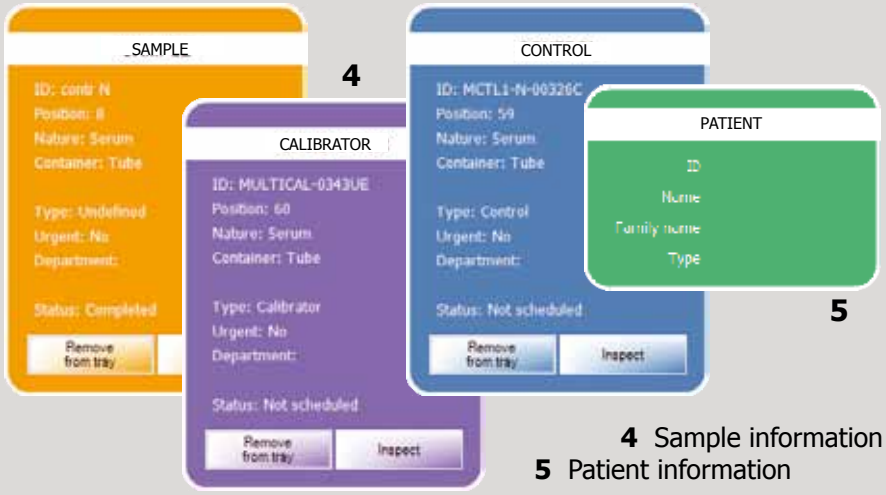


If the problem persists the error may also be caused by the erroneous configuration of the serial communcation port. In this case select the appropriate port from the "list ▾" provided and press "Retry".

Message boxes

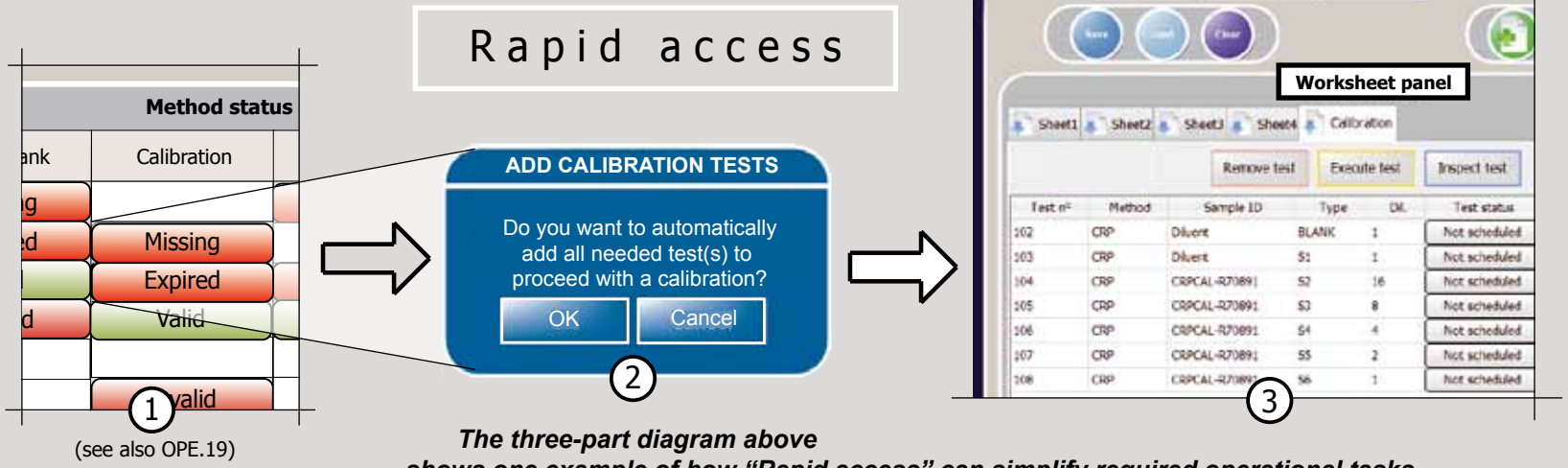


1 Error / Problem
2 Confirmation required
3 Warning (possible lose of data)



4 Sample information
5 Patient information

To "Rapid access" relevant current data and information, and working functions available in the system select any color coded item under "solution" or "status".



(see also OPE.19)

The three-part diagram above shows one example of how "Rapid access" can simplify required operational tasks. When either "Missing" or "Expired" is selected ("Calibration" column in "Method status") the message box "ADD CALIBRATION TESTS" is displayed and following an "OK-click" the entire list of tests required for calibration is automatically added to the "Worksheet panel".

The color coded buttons below show typical examples of additional "Rapid access" functions.

Solutions to problems

- Provide a new bottle of GLU-1
- Empty the waste tank and access the panel for confirmation
- Technical assistance required

Additional information

- Valid
- Completed
- Executing
- Result unusable

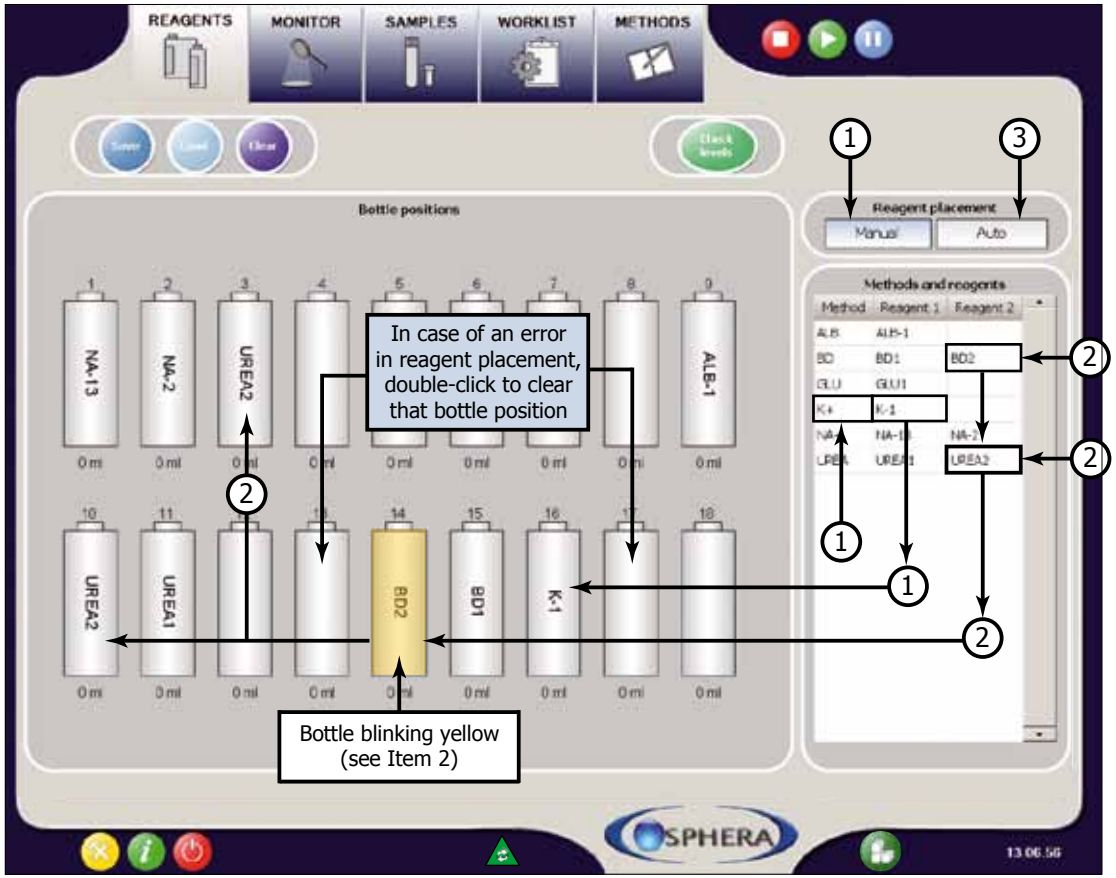
Error detection

- Expired
- Test aborted
- Predilution error
- Reag. blank error

Resources missing

- Not on board
- Reag.1 empty
- Sample empty
- Diluent empty

REAGENTS tab (REA)



Save

Save assigned positions and file bottle panel for reuse

Load

Retrieve and load a bottle panel from saved file

Clear

Clear displayed bottle panel

Check levels

Check liquid levels of panel displayed

Assign bottle positions by either "Manual" or "Auto" means

Manual

Assign reagent code(s) to bottle positions manually (see Items 1 and 2)

Auto

Assign reagent code(s) to bottle positions automatically (see Item 3)

Manual assignment of reagent bottle positions

1 To manually assign reagents to bottle positions, click on the method, then the reagent listed and touch-select an empty bottle to transfer the designated reagent code to that position.

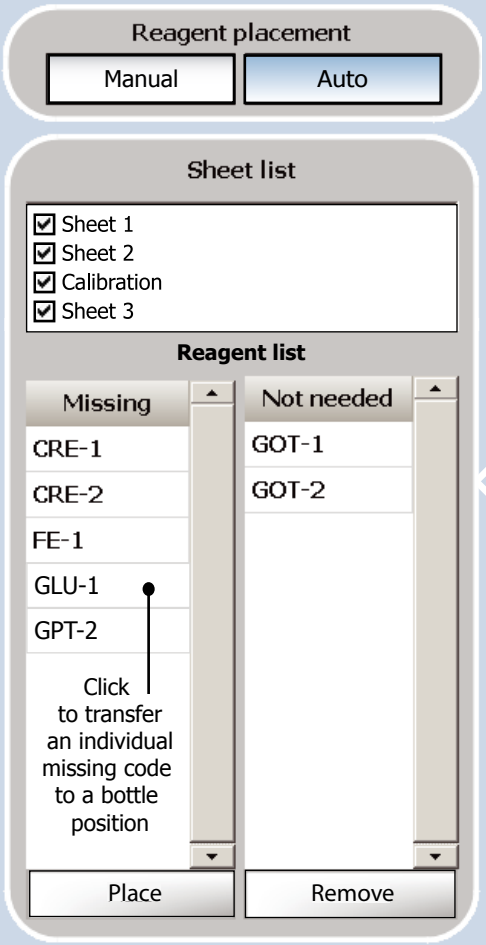
2 When a method requires a second reagent, click again and transfer *it* to an empty position.
Note: If a reagent code has already been assigned, that position in the bottle panel will blink yellow.

Auto assignment of reagent bottle positions

Worksheet list
All worksheets currently listed in the "Worklist tab" (see OPE.26)

An inventory is made of all sheets checked to monitor the status of reagent resources on-board and to compare them with current worklist requirements.

Reagent list
Reagents are identified as "Missing" or "Not needed" of those inventoried



3 Select "Auto" to assign "Missing" reagents to empty bottle positions and to remove those "Not needed" automatically .

Initially all sheets in the "Worksheet list" are checked and reagent requirements will be inventoried. If the inventory of a sheet is not required click to remove that checkmark.

Reagents that are "Missing" and those "Not needed" are shown. Touch-select "Place" to transfer all missing reagents to empty bottle positions and "Remove" to delete those not needed.

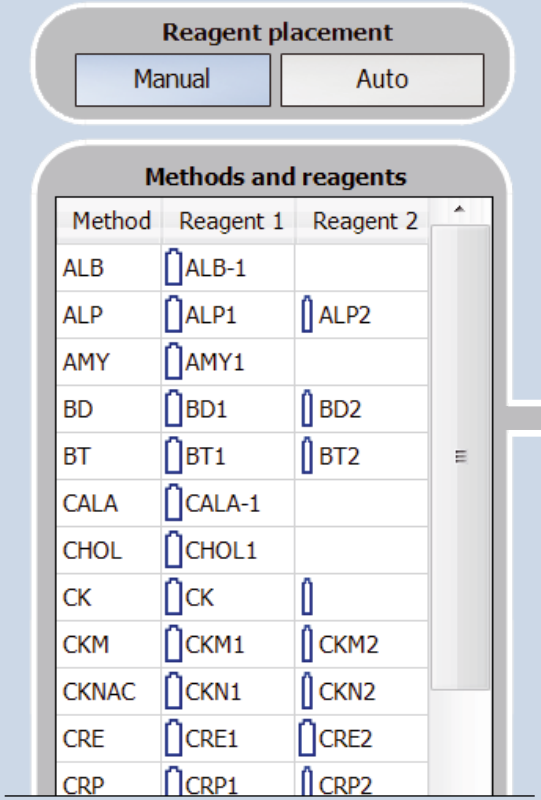
4 When all positions have been assigned, load the bottles of liquid reagents needed to positions indicated on the reagent tray.

Note: It is possible to load multiple bottles of the same reagent. Bottles which contain small amounts of liquid reagent remaining from previous tests can be used when loading the reagent tray. All bottles will be used beginning with the least full, then the next and finally the full bottles. Any number of methods may employ the same bottle of reagent.

REA, continued

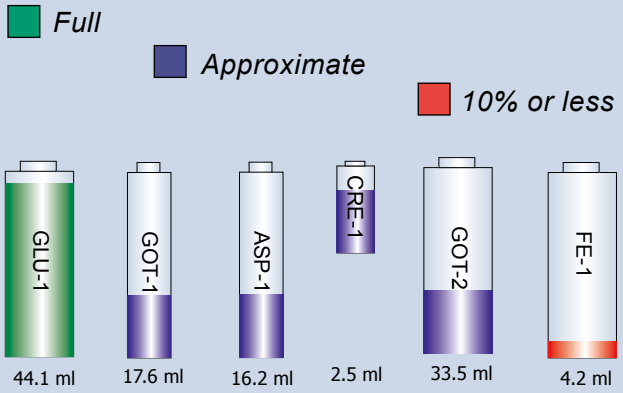
Reagents on board — Bottle positions / Liquid levels

When various size bottles (i.e. large, small) or cups are assigned to positions on the "Methods and reagents" panel, they are displayed in the "Bottle positions" panel.



The illustration below shows an enlarged version of how the actual liquid levels of reagents on-board appear in the "Bottle positions" panel.

"Bottle positions" in the current display can be used as a guide when actually loading bottles or cups on the reagent tray.



The exact positions on the tray and the use of the correct bottle sizes are manditory to ensure the accurate measurement of the volume of reagent liquid levels on-board.

NOTES

Liquid levels shown on the "Bottle positions" panel are constantly updated to permit real-time evaluation of reagents available on-board.

Bottle sizes are normally assigned by the administrator. However, this can also be done by the operator during routine work by adjustments to "Pipetting" (OPE.36). in method fields.

Normal reagent liquid volumes are: 50 and 24 ml for large and small bottles; 1-3 ml for cups.

5 "Monitoring / Checking liquid levels" of reagents currently on-board.

While the analyzer is "RUNNING" reagent liquid levels of tests being executed are constantly monitored. The user can touch-select any "Bottle position" in the panel at any time to request a liquid level check of *that* bottle.

NOTE
When the instrument detects a bottle or cup of reagent that has been newly replaced on the reagent tray (one found previously insufficient), all of the tests that were *stopped* for the lack of that specific reagent will be automatically rescheduled.

During the course of these procedures the liquid level of the diluent bottle is also measured.

When the analyzer is "STOPPED" choose any reagent bottle in the "Bottle positions" panel that you would like to verify, then touch-select "Check levels" to measure *that* liquid level.

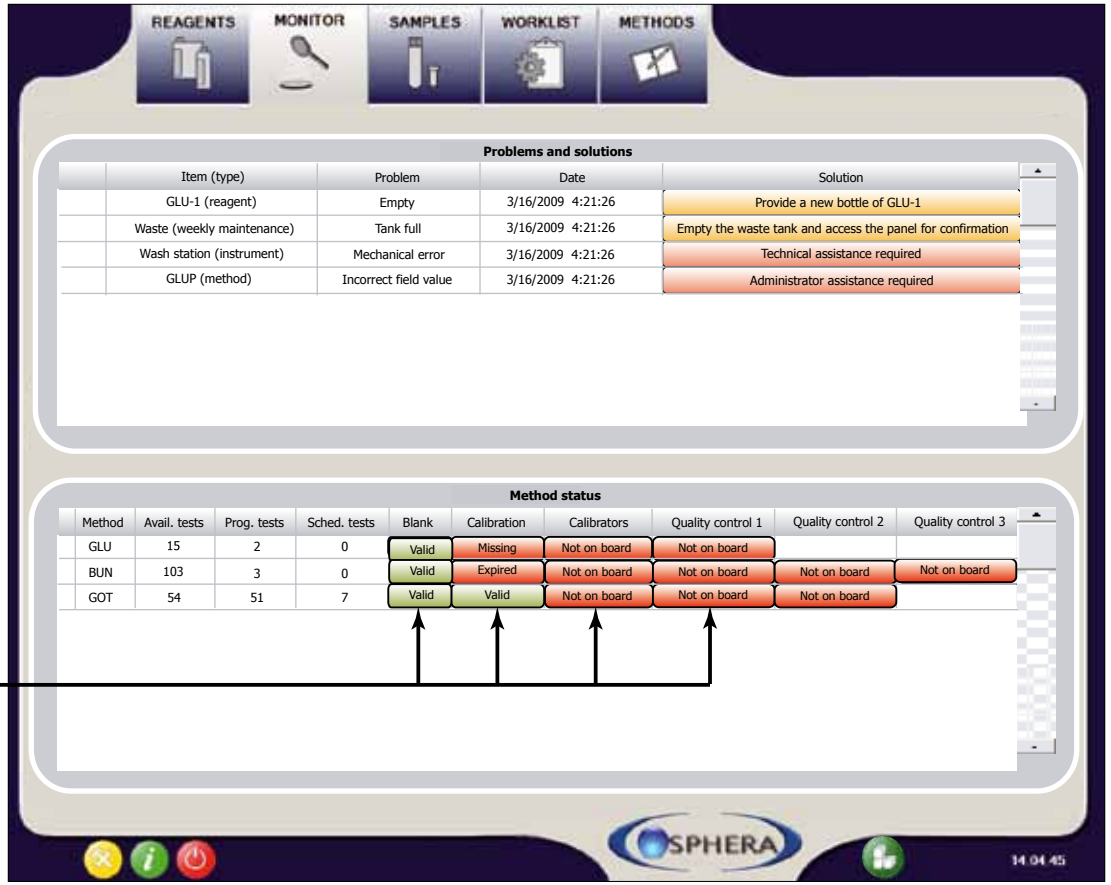
If no bottle selection is made, and "Check levels" is requested, the liquid levels of all reagents currently on-board will be measured.

REAGENT BARCODES
Reagent bottles with barcodes can be scanned using an external reader, recognized by the software HI and displayed in a special window provided in the "REAGENT tab". Users have only to click on an empty bottle position to trasfer that "reagent barcode".

MONITOR tab (MON)

O V E R V I E W

Constant monitoring of the status of all critical items that may interrupt the normal testing process. Once an anomaly is identified, a solution may be provided by using the "Rapid access" function (see also OPE.11)**.**


REAGENTS
MONITOR
SAMPLES
WORKLIST
METHODS
Problems and solutions
Item (type) | Problem | Date | Solution
GLU-1 (reagent) | Empty | 3/16/2009 4:21:26 | Provide a new bottle of GLU-1
Waste (weekly maintenance) | Tank full | 3/16/2009 4:21:26 | Empty the waste tank and access the panel for confirmation
Wash station (instrument) | Mechanical error | 3/16/2009 4:21:26 | Technical assistance required
GLUP (method) | Incorrect field value | 3/16/2009 4:21:26 | Administrator assistance required
Method status
Method | Avail. tests | Prog. tests | Sched. tests | Blank | Calibration | Calibrators | Quality control 1 | Quality control 2 | Quality control 3
GLU | 15 | 2 | 0 | Valid | Missing | Not on board | Not on board
BUN | 103 | 3 | 0 | Valid | Expired | Not on board | Not on board | Not on board | Not on board
GOT | 54 | 51 | 7 | Valid | Valid | Not on board | Not on board | Not on board
SPHERA
14.04.45

Problems and solutions
Identifies problems concerning the instrument and indicates possible solutions for the user.

Method status
Provides information for each method programmed; Indicates scheduled and available tests, and the status of reagent blank, calibration, calibrators and quality control.

Method status
("Rapid access")

Blank / Calibration

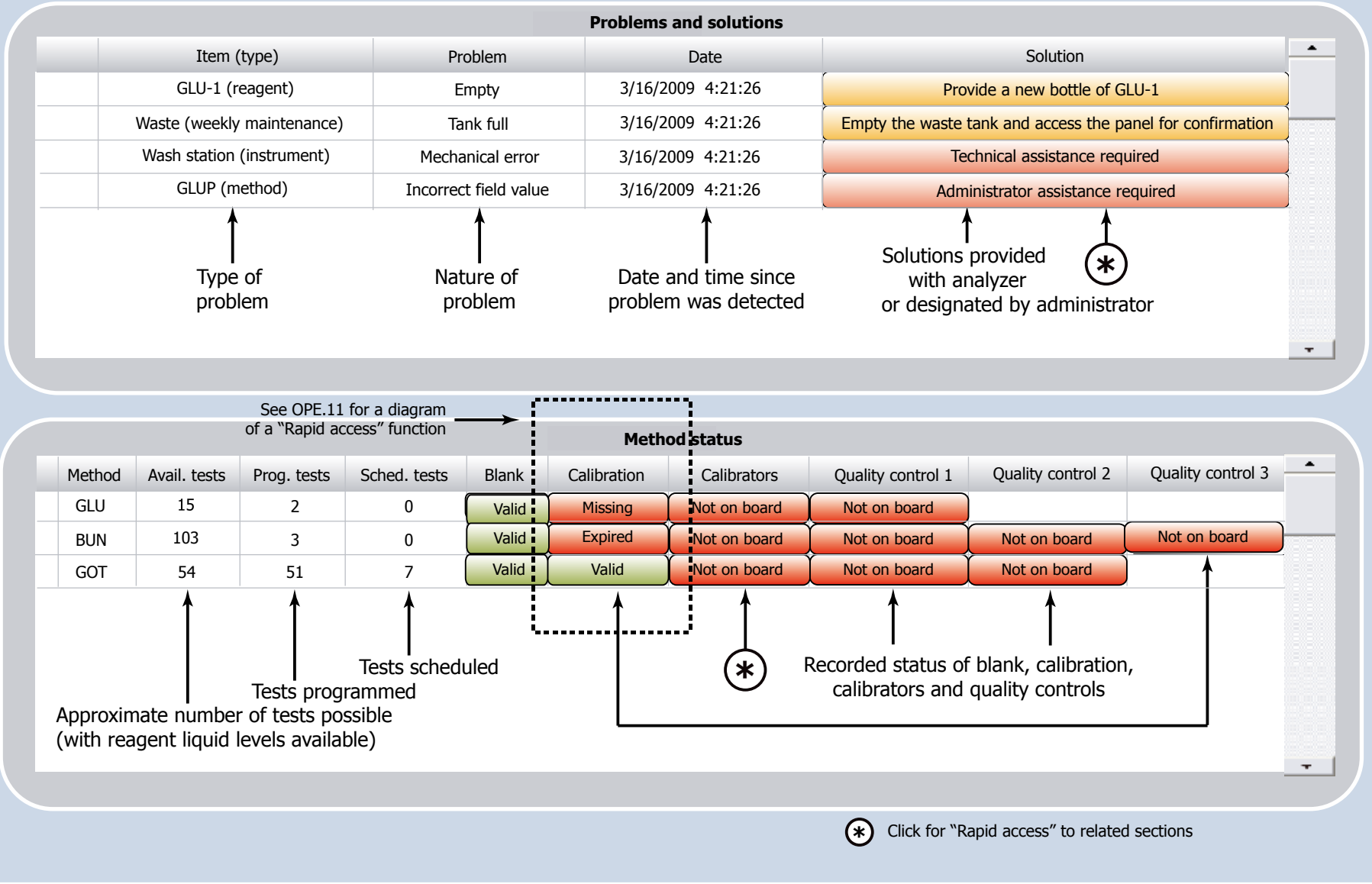
Missing	Has not been executed
Expired	No longer valid *
Valid	Has been executed and is still valid
Invalid	Unusable (Reagent BLANK / Calibration)

* Possible drift in chemical characteristics of reagent

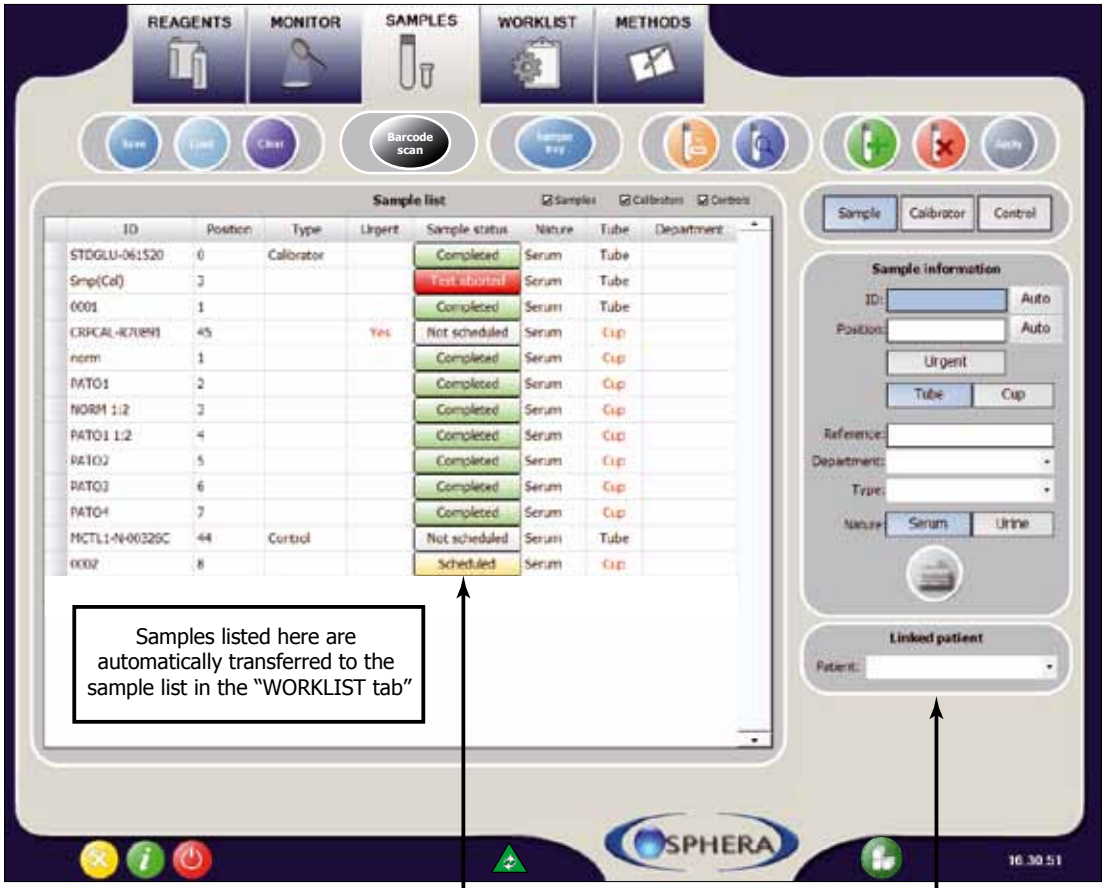
Calibrators / Quality control **

On board	Specified and present
Expired	Specified but no longer valid
Not on board	Specified but not present
Method error	Not specified in method

** User's may elect to apply quality controls at any time to monitor the accuracy of ongoing analyses


Problems and solutions
Item (type)
Problem
Date
Solution
GLU-1 (reagent)
Empty
3/16/2009 4:21:26
Provide a new bottle of GLU-1
Waste (weekly maintenance)
Tank full
3/16/2009 4:21:26
Empty the waste tank and access the panel for confirmation
Wash station (instrument)
Mechanical error
3/16/2009 4:21:26
Technical assistance required
GLUP (method)
Incorrect field value
3/16/2009 4:21:26
Administrator assistance required
Type of problem
Nature of problem
Date and time since problem was detected
Solutions provided with analyzer or designated by administrator
See OPE.11 for a diagram of a "Rapid access" function
Method status
Method
Avail. tests
Prog. tests
Sched. tests
Blank
Calibration
Calibrators
Quality control 1
Quality control 2
Quality control 3
GLU 15 2 0 Valid Missing Not on board Not on board
BUN 103 3 0 Valid Expired Not on board Not on board Not on board Not on board
GOT 54 51 7 Valid Valid Not on board Not on board Not on board
Approximate number of tests possible (with reagent liquid levels available)
Tests programmed
Tests scheduled
Recorded status of blank, calibration, calibrators and quality controls
Click for "Rapid access" to related sections

SAMPLES tab (SAM)



Save

Save and file a sample list for reuse (without related tests)

Load

Retrieve and load a sample list from saved file (without related tests)

Clear

Clear displayed sample list (with related tests)

Add / Remove a sample

Apply

Apply modified data to selected sample in list

Display work form for sample report

Display work form for sample inspection

Sample tray

Display work form showing tray positions for samples, calibrators and controls

Barcode scan

Execute a complete scan of "sample barcodes"

Sample status *("Rapid access")*

Routine

Not Scheduled	One or more tests of that sample are waiting for confirmation
Scheduled	All tests of that sample have been scheduled
Executing	One or more tests of that sample are being executed
Completed	All tests of that sample have been completed and are correct

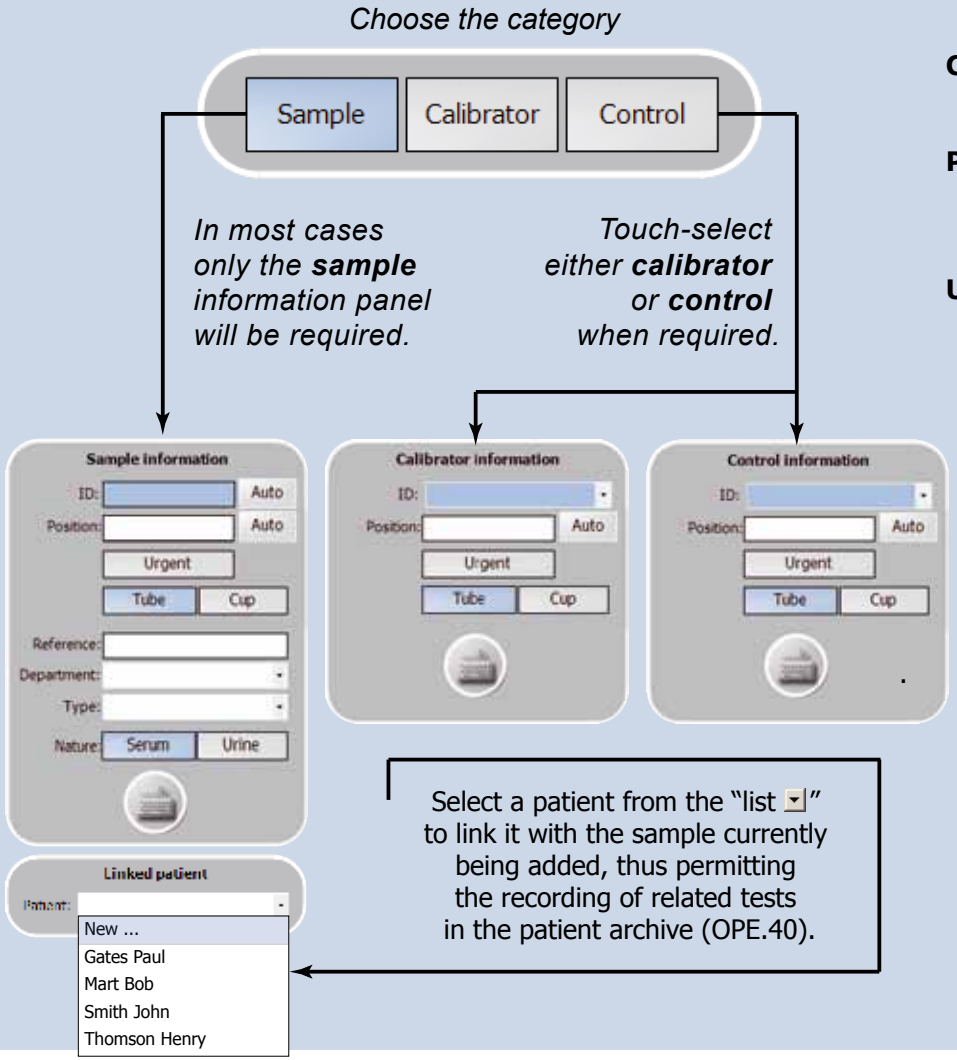
Sample errors

Sample empty	Sample remaining is insufficient for testing
Test aborted	One or more tests of the sample have been aborted

Linked patient

Establish links between patients and samples for analyzer archives. See OPE.40 for a description of how this feature works.

1 Identify a category (Sample, Calibrator, Control) and enter data required (see adjacent list).



Sample identification (ID)
If an ID has been provided with the sample, click on the ID field and enter it using the touch-screen "Keyboard".
If no ID is provided, press "Auto" and the next available ID number will be entered.

Calibrator / Control identification (ID)
Access the "list" and select from those provided.

Position *
Press "Auto" for next available position.
(Enter specific positions using the touch-screen "Keyboard".)

Urgent *
To identify samples or controls of an urgent nature.
(Calibrators are always urgent and are auto-tagged as such.)

Tube / Cup *
Identify sample container to be used.

Reference **
Enter a reference name for identification convenience.

Department / Type **
Access the "list" and select from those provided.

Nature **
Select serum or urine.

* sample, calibrator, control
** sample only

2 To add a new sample, (after data fields are complete), press the **"Plus"** icon to transfer that information.

Sample list management

SAM, continued

3 Continue until all sample data required for the current work schedule has been entered and transferred to the sample list.

Initially all categories are checked (samples, calibrators, controls). If not required click to remove that checkmark.

To **delete a line** (Item 4), **change an entry** (Item 5), **inspect a sample** (Item 6) or **print test results** (Item 7)

... first touch select the line in question and then perform the operation

When no designation is indicated in the "Type" column the sample type has not been specified

Sample list ☑ Samples ☑ Calibrators ☑ Controls

ID	Position	Type	Urgent	Sample status	Nature	Tube	Department
NORM 1:2	4	Control		Completed	Serum	Cup	
CRPCAL-R70891	3	Calibrator	Yes	Test aborted	Serum	Tube	
0002	1	Male	Yes	Completed	Serum	Tube	Pediatry
0001	2	Female	✱	Completed	Serum	Cup	
0003	9			Not scheduled	Serum	Tube	Surgery
PATO-1	45	Control		Not scheduled	Serum	Cup	

There are no reserved positions.
Urgencies, Samples, Calibrators and Controls are positioned together in normal tube configuration and in any sequence assigned by the operator in the course of programming work.

✱ Click for "Rapid access" to related sections

4 To delete an entire line from the sample list, touch select that line and press the **"Remove"** icon.

5 To change an incorrect entry in the sample list, touch select that line, make the necessary adjustment and press **"Apply"** to add it.

SAM, continued

1

A line item selected in the "SAMPLE tab" (OPE.20) will be entered here under "Information"; Other relative data will be displayed throughout the current work form

2

Subsequent selections of other samples can be accessed here without returning to the "SAMPLE tab"

3

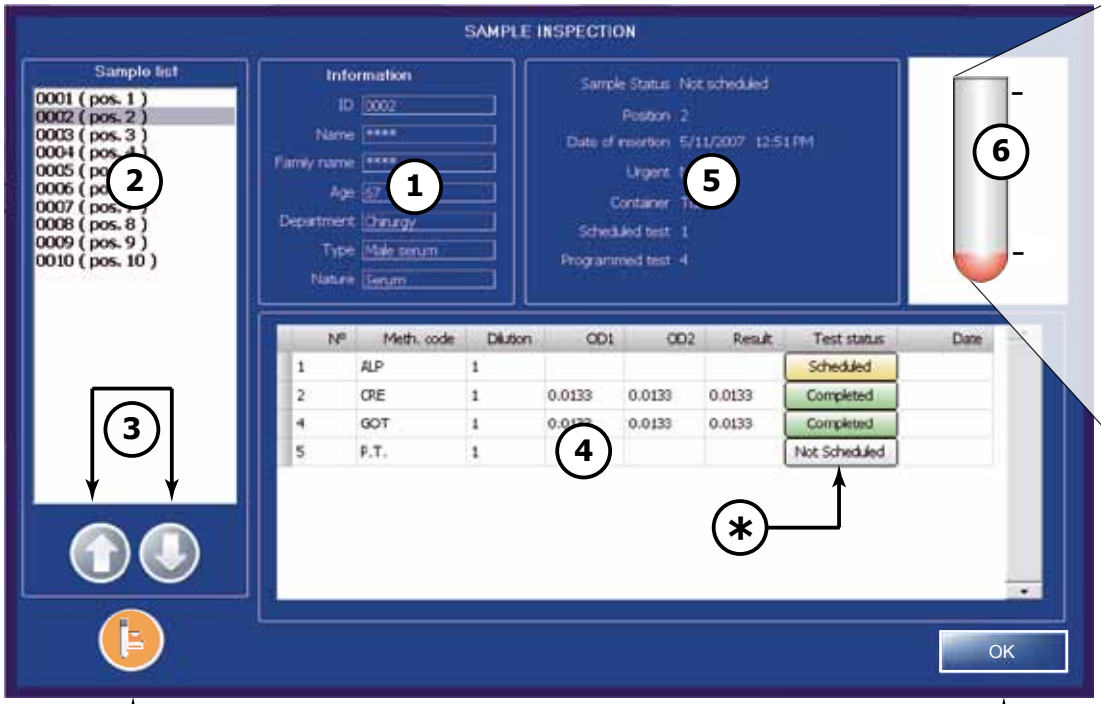
Next sample; Previous sample

4

Tests listed showing information on method code, dilution, OD, result, status, date

(*) click for "Rapid access" to "TEST INSPECTION"

6 To access accurate information of a sample, select that line in the sample list and press the **"Inspect"** icon to display the "SAMPLE INSPECTION" work form.

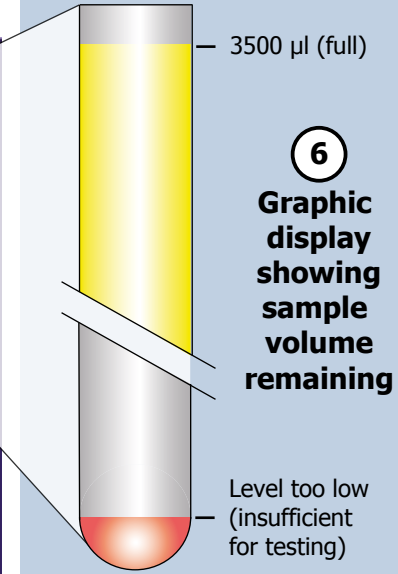


Sample inspection

An overview of sample information featuring a graphic display showing the remaining sample volume for easy monitoring of the current level.

5

Additional useful information



6

Graphic display showing sample volume remaining

7

Access "SAMPLE REPORT"

8

Exit "SAMPLE INSPECTION" work form

SAM, continued

1
A line item selected in the "SAMPLE tab" (OPE.20) will be entered here under "Information"; Other relative data will be displayed throughout the current work form

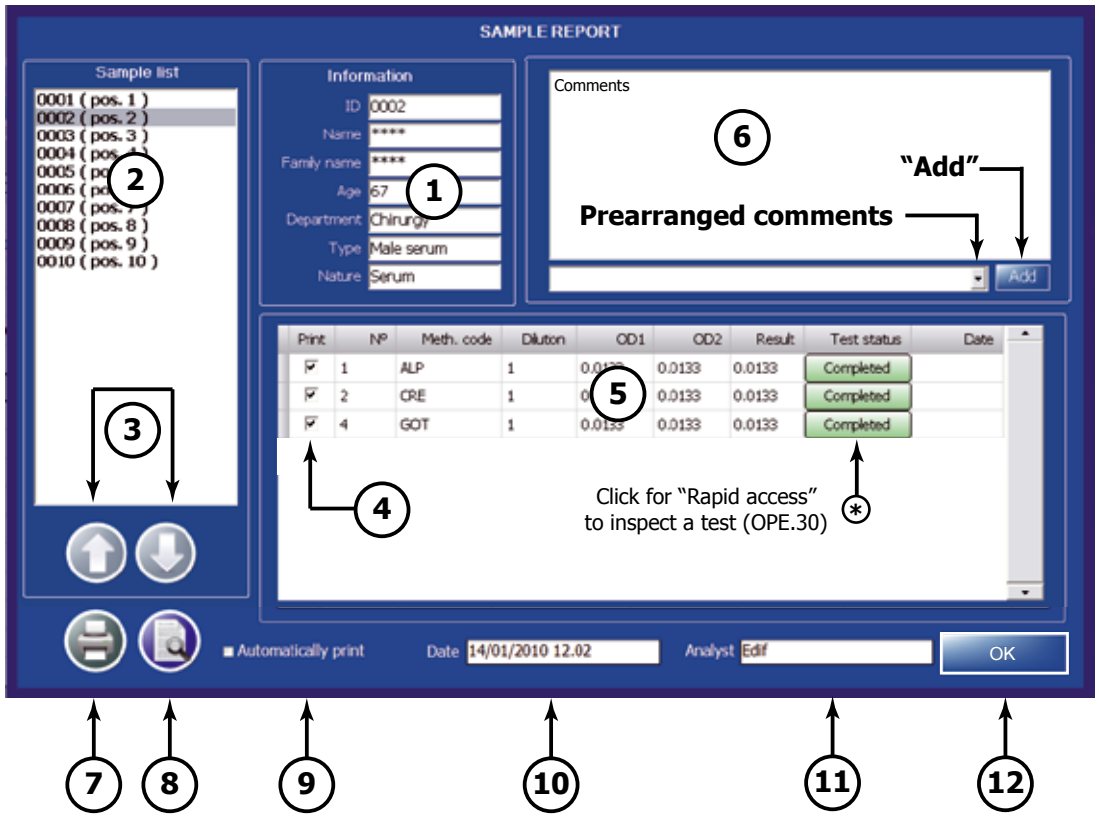
2
Subsequent selections of other samples can be accessed here without returning to the "SAMPLE tab"

3
Next sample; Previous sample

4
Checked tests will be included in the report

5
Tests listed *that have been completed* showing information on method code, dilution, result, status, date

7 If a printout of test results is required, select that line in the sample list and press the **"Print"** icon to display the "SAMPLE REPORT" work form.



Sample report

With this form it is possible to select the results to be shown and to insert additional comments in the printout.

6
Space reserved for comments and observations; Prearranged comments can be selected and added to the "Comments" box by pressing "Add"

7
Print sample report

8
Preview the report

9
Check to automatically print report when all tests for that sample have been completed

10
Date and time

11
Name of analyst

12
Exit
"SAMPLE REPORT" work form

SAM, continued

(1) (1a)

Touch select any tray position to display color coded information panels;

Remove from tray | Inspect

Commands to remove a sample or display the "SAMPLE INSPECTION" work form

(2)

List of samples with no assigned tray positions; Activate any item and touch-select a tray position to place that item

Place all (3)

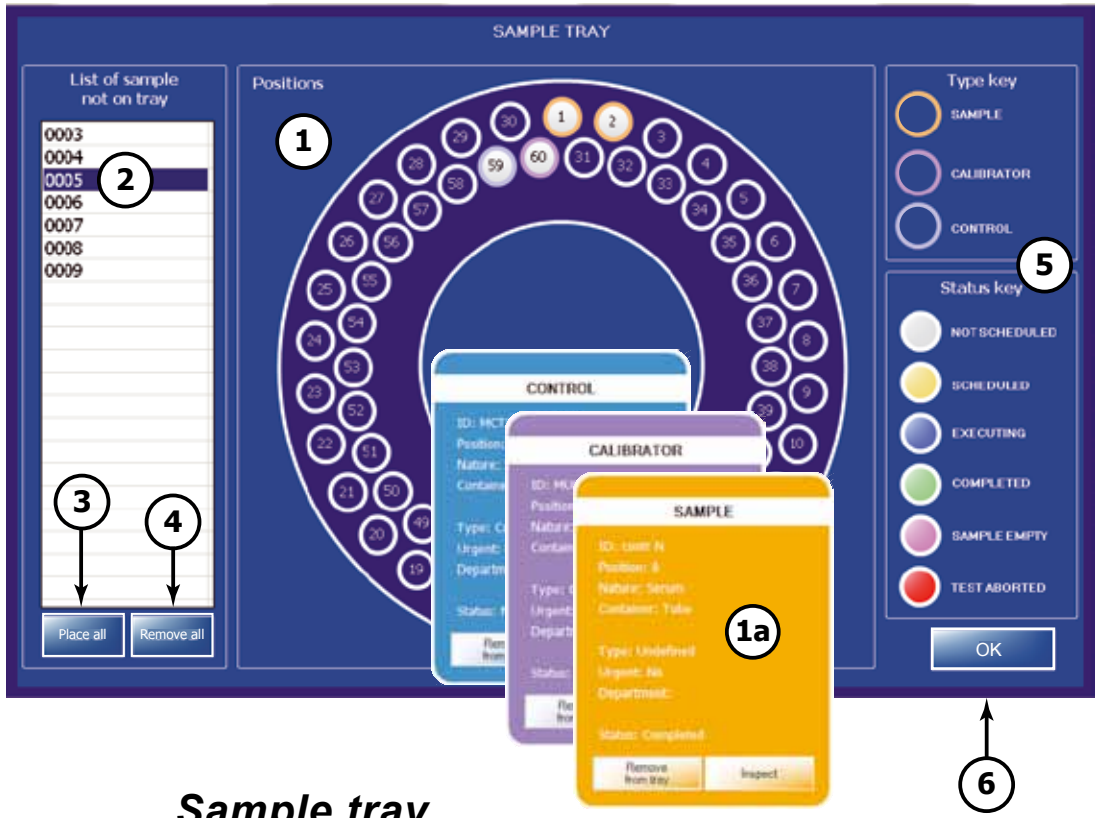
Auto placement of samples listed to any empty tray positions

Remove all (4)

Remove all samples from the tray

8 This work form shows the positions assigned to urgencies, samples, calibrators and controls, with the color coded status of each.
It can be displayed by pressing **"Sample tray"**.

Sample tray



Sample tray

This effective management tool makes it is possible to remove or place samples, and monitor type, location and status of tests displayed.

(5)

Color coded key permits identification of the position of samples/urgencies/ calibrators/controls, and the status* of each in the testing process

Code examples

SAMPLE
(orange ring)
+
COMPLETED
(green center)
=
SAMPLE COMPLETED
(orange and green)

* see descriptions of "Sample status", OPE.20

(6)

Exit
"SAMPLE TRAY" work form

WORKLIST tab (WOL)

Save

Save and file
all worksheets for reuse
(with related samples)

Load

Retrieve and load
worksheets from saved file
(with related samples)

Clear

Clear all worksheets
(without related samples)

Unlimited worklists can be managed simultaneously.

Create
a new worksheet

Remove
worksheet selected

Run all tests
on the worksheet
selected

Print a report
of the worksheet
selected

Test status
("Rapid access")

Routine

Not Scheduled	Test programmed / Waiting for confirmation
Scheduled	Test confirmed / Waiting for execution
Executing	Test in process
Completed	Test result usable
Result unusable	Test result unusable
Result edited	Test result edited by user

Instrument errors

Predilution error	Predilution failed
Mechanical error	Mechanical problem
Cover open	Cover opened during run
Optical error	Reading failed

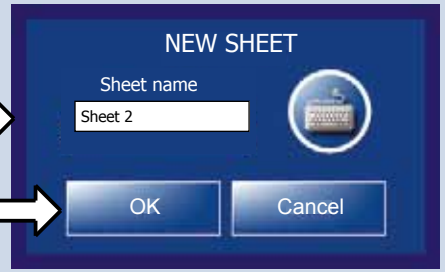
Resource errors

Reag. 1 missing	Not assigned on reagent panel
Reag. 2 missing	Not assigned on reagent panel
Reag. blank error	Reagent usability range exceeded
Reag. 1 empty	Reagent assigned insufficent
Reag. 2 empty	Reagent assigned insufficent
Sample empty	Sample provided insufficent
Diluent empty	Diluent provided insufficent

Worksheet management

1 To create a new sheet of tests touch-select **"Plus"** and activate the "NEW SHEET" window.

Type in a name or other designation suitable to identify the new page and and then press "**OK**"



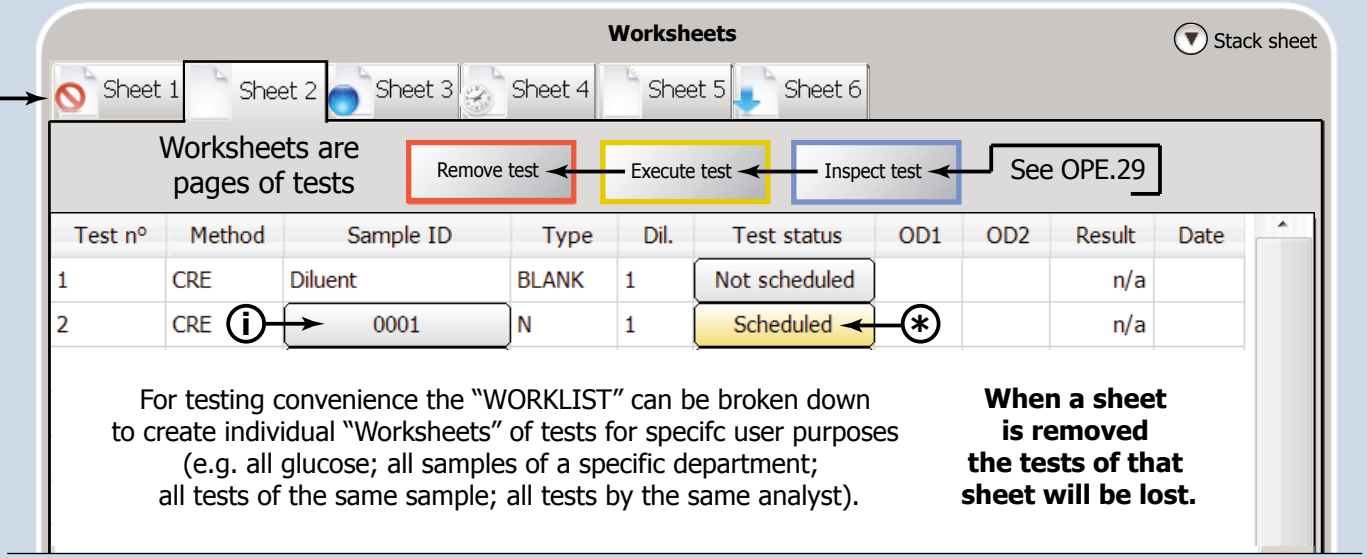
2 To remove a sheet of tests activate that sheet and touch-select **"Minus"**.

3 To run a sheet of tests activate that sheet and touch-select **"Execute"**.

4 To print a sheet of tests activate that sheet and touch-select **"Print"**.

Sheet status

- **Not scheduled**
- **Scheduled**
- **Executing**
- **Completed**
- **Aborted**



ⓘ Click any "Sample ID" to display the "Message boxes" showing relevant sample and patient information (see Items 4 and 5, OPE.12)

⊛ Click for "Rapid access" to related sections

Test management

5 Choose a category (Test, Calibration, QC) to add that item to a selected sheet.

Identify the item

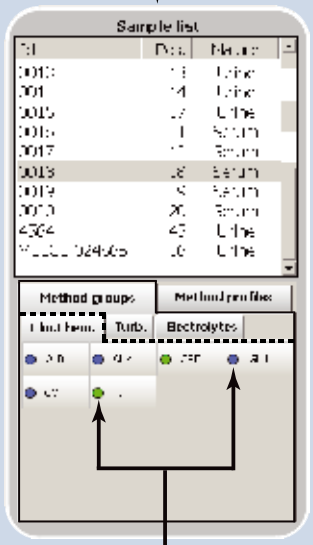
WOL, continued

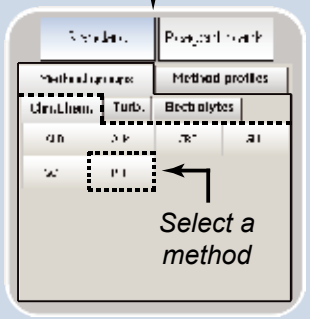
Test | Calibration | QC

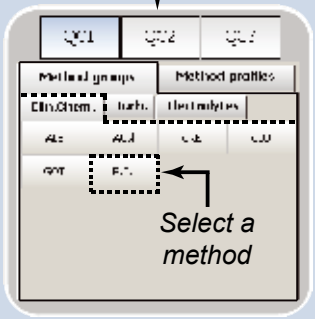
For a test select both a sample and a method

For calibration select standard or reagent blank and a method (this includes a complete list of tests)

For quality control select one or more QC listings and a method





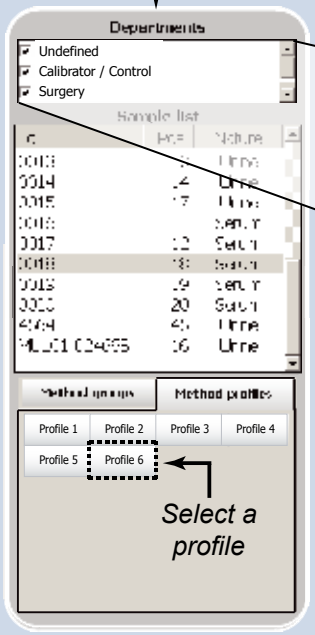


Method groups. Touch-select a method code to add that item to the selected page of tests.

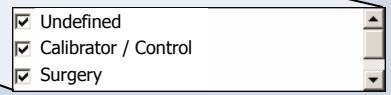
Method profiles. Touch-select a profile to add the page selected to the complete list of tests linked to that item

Blue: test not programmed
Green: test programmed

Departments
This panel appears above the "Sample list" when departments have been set-up by the administrator. Only the samples in checked categories will appear in the "Sample list" thus reducing user search-and-find operations.

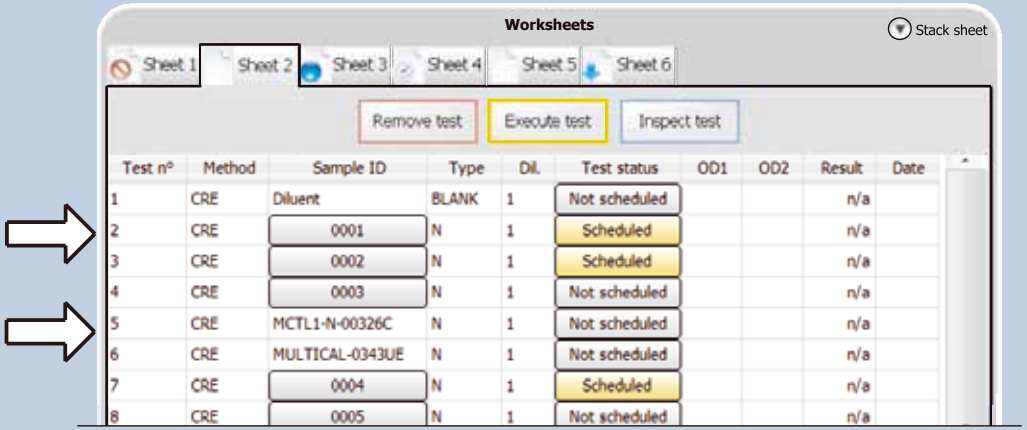


If a listing is not required click to remove that checkmark



The administrator of your laboratory has managed method profiles for this instrument to simplify work routine. Users can add a complete list of tests to a worksheet with a single click avoiding long programming sessions.

Note that method groups and profiles are available in all panel variations



6 Activate any test line(s) on a worksheet of tests to either "Remove, Execute or Inspect" the line(s) indicated and then touch-select the required option.

Remove test

Delete selected test(s).
Note: when a test is removed it will be lost.

Execute test

When "Execute test" is activated ...

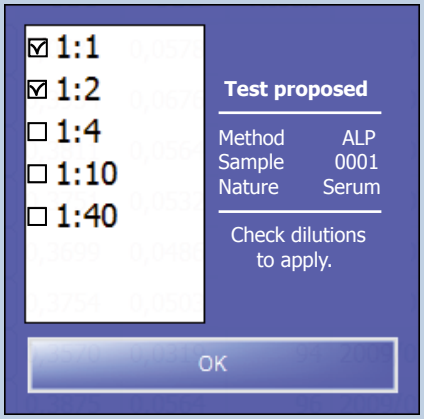
- Non-scheduled tests will be scheduled and added to the work queue.
- Completed tests will be copied (replicated). The copies will be inserted in the worksheet (possibly diluted) and executed.
- Tests in error will be run again.

Inspect test

Access "Test inspection" work form (see OPE.30).

D I L U T I O N S

If more than one dilution is available for the method selected, a box will be shown for the selection of the dilution rate.



Rates that are checked will be inserted in the current worksheet.

NOTE
If the result of a test is unusable, it may be possible that the sample is too concentrated. When this is the case the test should be replicated with an appropriate dilution rate based on the previous result.

WOL, continued

1

A line item selected in the "WORKLIST tab" (OPE.26) will be entered here under "Information"; Other relative data will be displayed throughout the current work form

2

Subsequent selections of other tests can be accessed here without returning to the "WORKLIST tab"

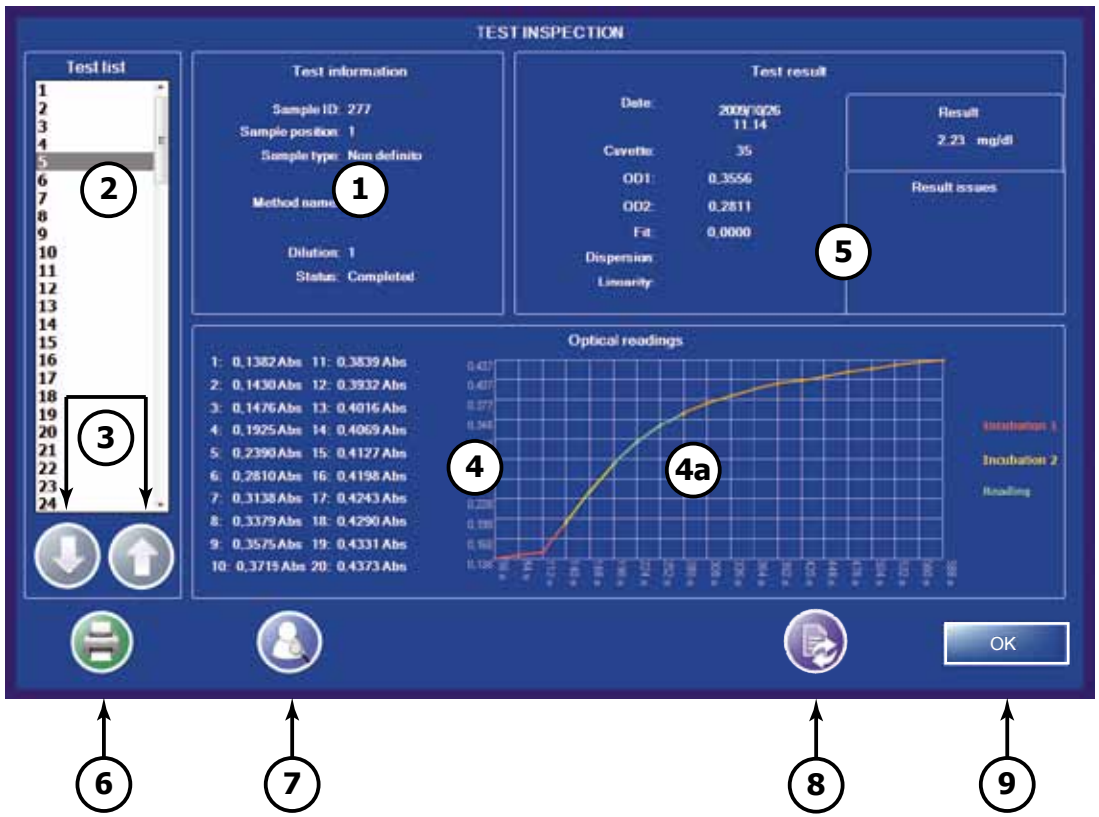
3

Next test; Previous test

4 **4a**

Test result readings in Abs with a graphic representation; Readings plotted here represent the trend of ODs during test execution

7 To inspect the result of a test on a sheet select that test line and press **"Inspect test"** to display the work form.



Test inspection

An overview of test information with a graphic of test readings and result considerations. A recalculation of test results is possible.

5

Additional useful information about the test result (includes ODs, date and eventual listings of issues encountered during testing)

6

Print test report

7

Access
"SAMPLE INSPECTION"

8

Within 24 hours from test execution, if either calibration or blank were faulty, and thus were adjusted, it is possible to request a new result calculation with the latest calibration

9

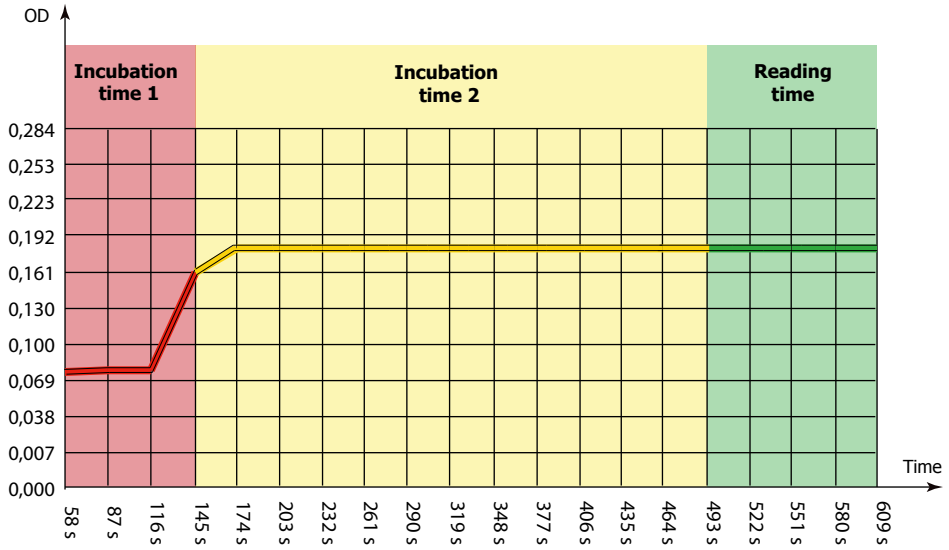
Exit
"TEST INSPECTION" work form

4a

The color coded chart below indicates the test timings followed by the instrument for a single test

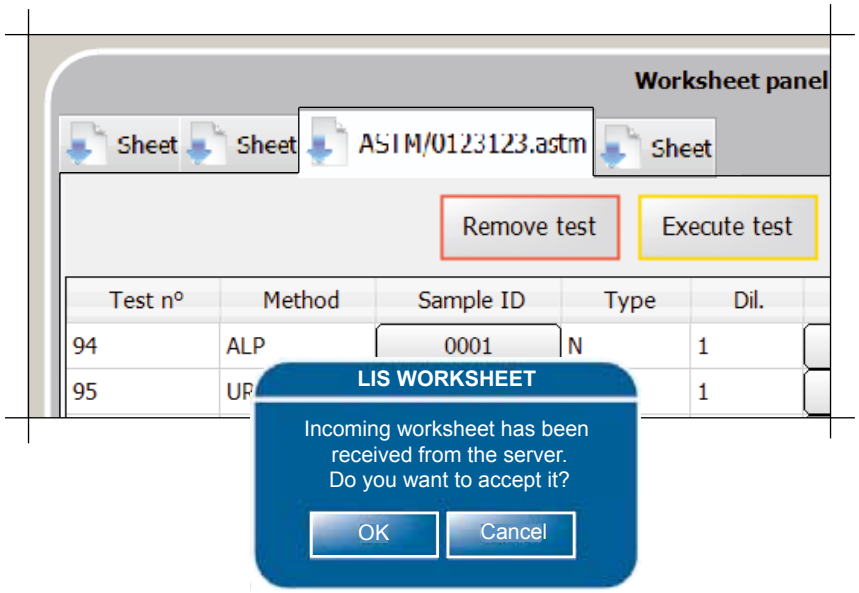
* * *

Operators familiar with the trends normally associated with the reaction curves of analyses may be in a unique position to contribute their insight regarding the validity of tests executed on specific samples. This can provide a valuable asset which is particularly effective when testing samples with specific pathological characteristics.



Reactions are accurately followed by readings taken every machine cycle for each test during the entire testing process.

LIS management system



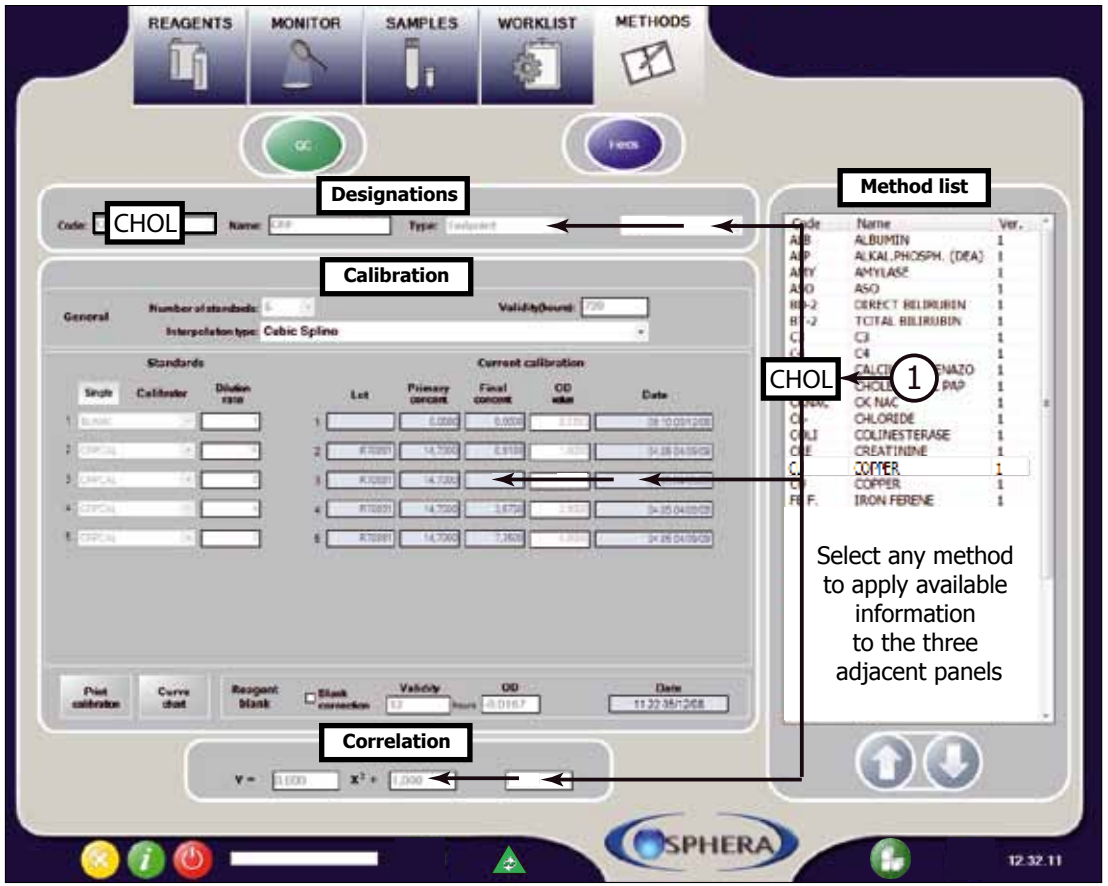
If software for the management of the laboratory (LIS) has been set-up to work in tandem with the instrument, it is possible to receive worksheet data from the central computer. When this happens a message box requesting confirmation by the operator will be displayed in the middle of the screen. Upon "OK", LIS information will be transferred to a normal worksheet and executed. Once completed the results will be sent automatically to the central computer.

METHODS tab (MET)

Designations
Information pertaining to the method selected

Calibration
Information used to build calibration tests (see OPE.33)

Correlation
Information used to adjust results with correlation models (see OPE.35)



Fields
Access the "METHOD FIELDS" work form to check the working parameters of the selected method (see OPE.36)

QC
Access the "QUALITY CONTROL" work module to assign controls to each method and check QC results

See also OPE.35 for a special note

1 Select a method in the "Method list" and the appropriate data will be displayed under "Desigations, Calibration" and "Correlation".

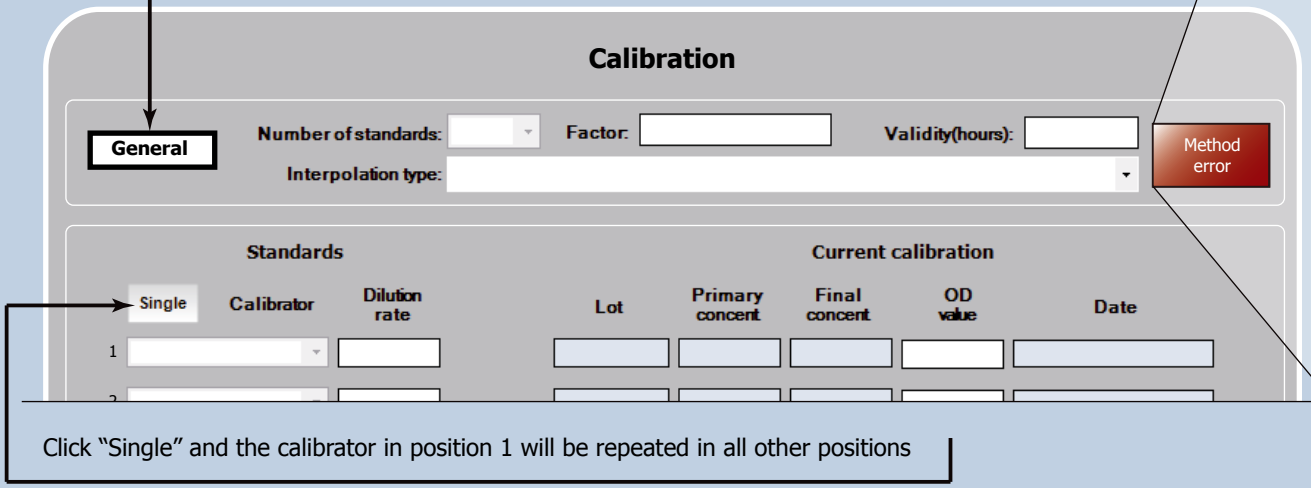
This information forms the basis for functions critical for testing (e.g. readings and calculations, interpolations, testing processes, timings, volumes).

The methods that are installed on this instrument have been set by your administrator.
They have been developed for specific reagent types.
During the testing process if there is any doubt concerning the quality of the reagent used, bring this to the attention of your administrator.

Calibration

Calibrations are the means by which the instrument transforms ODs (optical density values) into interpretable results (concentrations). It can be a linear function (factor) or it can be a non-linear function described by multiple points (standards). To ensure accurate results it is mandatory to execute a calibration of the method each time it is requested by the system.

Number of standards to be used for the calibration
Factor of multiplication for result concentration
Validity of the calibration expressed in hours
Interpolation type used for calculation



Click "Single" and the calibrator in position 1 will be repeated in all other positions

METHOD ERRORS

Invalid filter
A filter with the wavelength inserted is not mounted on the instrument

Invalid calibration of method filters
The optical calibration at "Start-up" has failed

Error in calibration curve standards
One or more standards of the curve are invalid

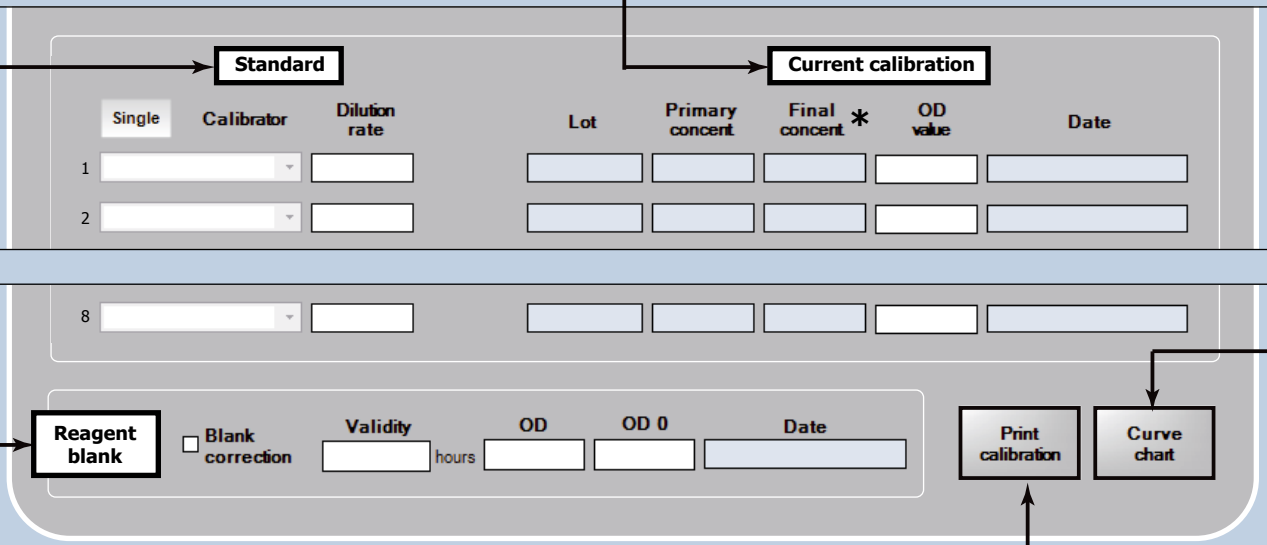
Error in reagent BLANK ranges
Blank calibration values are out of range

Error in calibration curve ODs
The OD values of calibration are out of range

Calibration, continued

Lot currently in use for the selected calibrator
Primary concentration of the selected lot
Final concentration* used for the standard
OD value of the last calibration in absorbances (Abs)
Date of execution of the last calibration

Calibrator used for the standard
Dilution rate to be applied to the standard



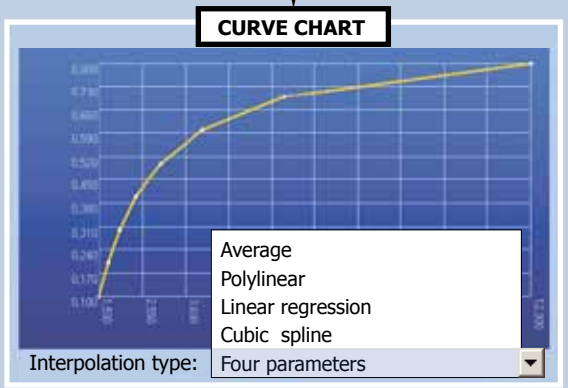
*

Final concentration = Primary concentration ÷ Dilution rate

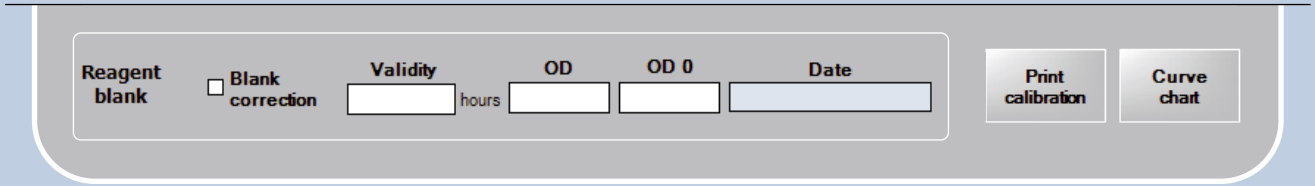
Touch-select curve chart, access " listings", select interpolation type to be used for calculations

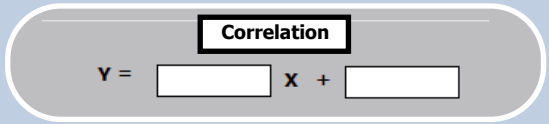
Blank correction used in result calculation if checked
Validity of the blank in hours
Blank OD values in absorbances (Abs)
Date of execution of the last blank correction

Print a report showing the current calibration status and chart



If the calibration of a method is no longer valid the user will be alerted both in the "MONITOR tab" (OPE.18) and in the test creation process in the "WORKLISt tab" (OPE.26). In this case it will be necessary to build new calibration tests for the required method to be executed.



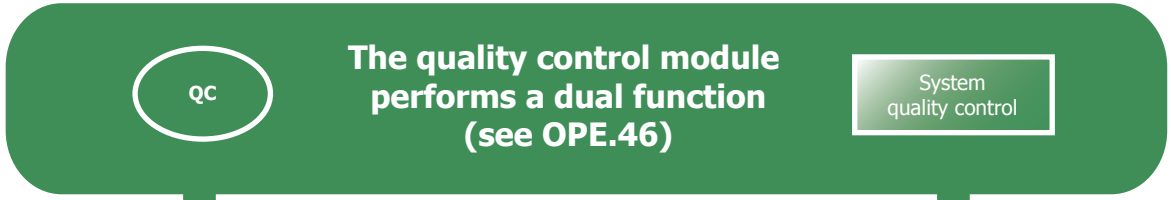


MET, continued

Result correlation

This operation, configured by the administrator of the laboratory, is used to align the result obtained during testing with other results statistically obtained from instruments of reference. This process may help to improve the accuracy level of the instrument in certain cases.

A special note on quality control



This module can be accessed from the "METHODS tab" to assign the controls that are used during the execution of QC tests and to monitor their status.

It can also be accessed to monitor the overall status of the entire system (e.g. accuracy and performance indicators).

MET, continued

1
PIPETTING
Codes of reagents and diluents to be used; Bottle sizes; Liquid volumes pipetted

2
TIME
The time scheduled for the test reaction (i.e. between sampling and reading)

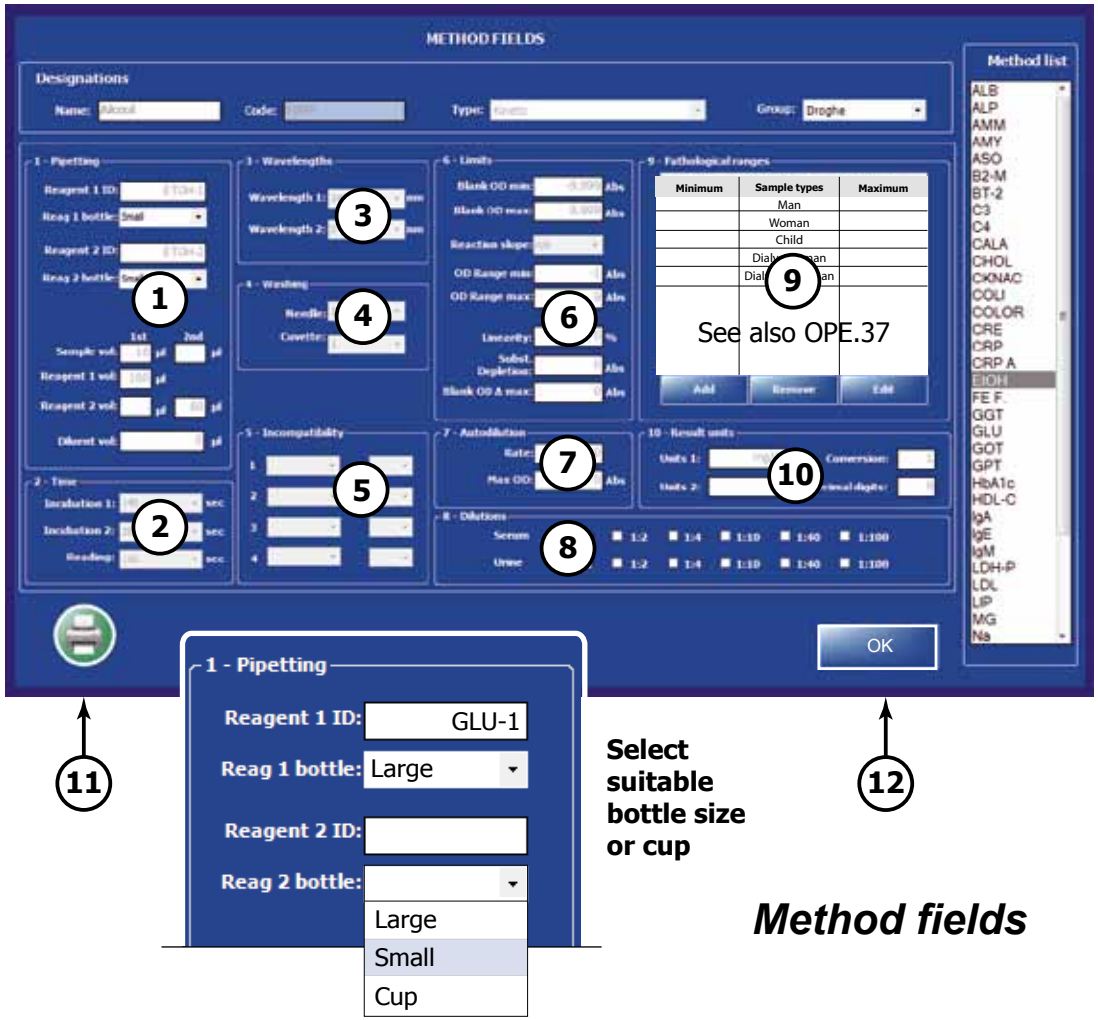
3
WAVELENGTHS
Each method requires specific wavelength(s) for the reading(s) to be performed

4
WASHING
Programmed intensity of washings required for each test sequence

5
INCOMPATIBILITY
Number of cycles that are skipped in the work queue to avoid contamination owing to incompatible reagent proximity

4 To inspect or adjust a method item, press **"Fields"** to display the "METHOD FIELDS" work form.
Then, select the desired line from the method list to automatically apply the relevant information (which will define all testing procedures).

Fields



Method fields

6
LIMITS
Working limits for results validity

7
AUTODILUTION
Dilution rate used in the event of automatic test repetition

8
DILUTIONS
Serum and urine rates

9
PATHOLOGICAL RANGES
Min / Max values for various sample types

10
RESULT UNITS
Allows access to appropriate measurement units for the analysis being performed

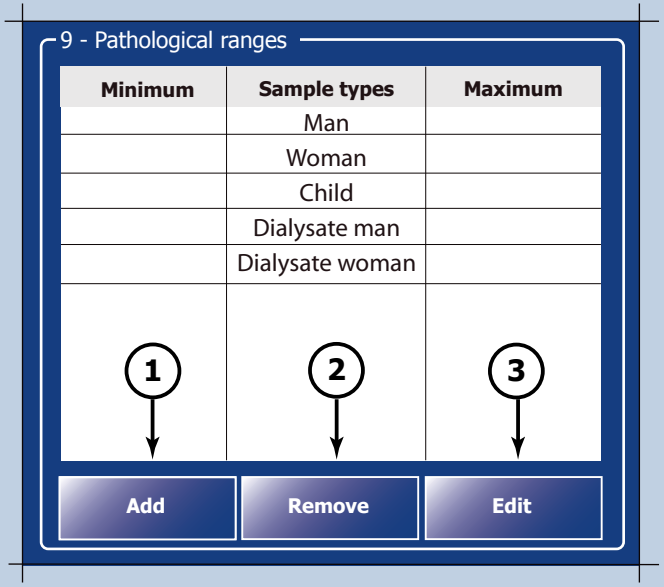
11
Print report of selected method

12
Exit
"METHOD FIELDS" work form

A list of sample types may be set-up by the administrator.

In the test reports, if a result is lower than the minimum normal value "<L" is indicated. If a result is higher than the maximum normal value ">H" is indicated.

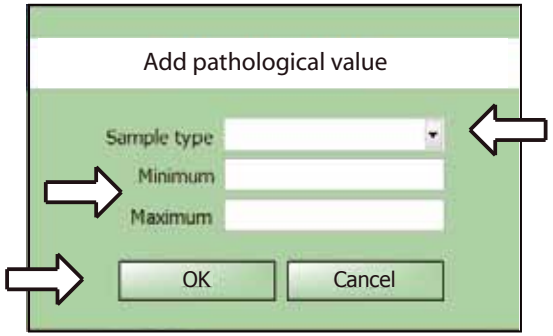
Minimum and maximum normal reference values are expressed in primary units.



MANAGEMENT OF PATHOLOGICAL RANGES AND LIMITS

1

To add a new "Sample type" press **"Add"**, select from the "list ▾" of previously added types (or enter a new value for specific use) with the maximum and minimum range, then press **"OK".**



2

To remove a type, select a line item and press **"Remove"**.

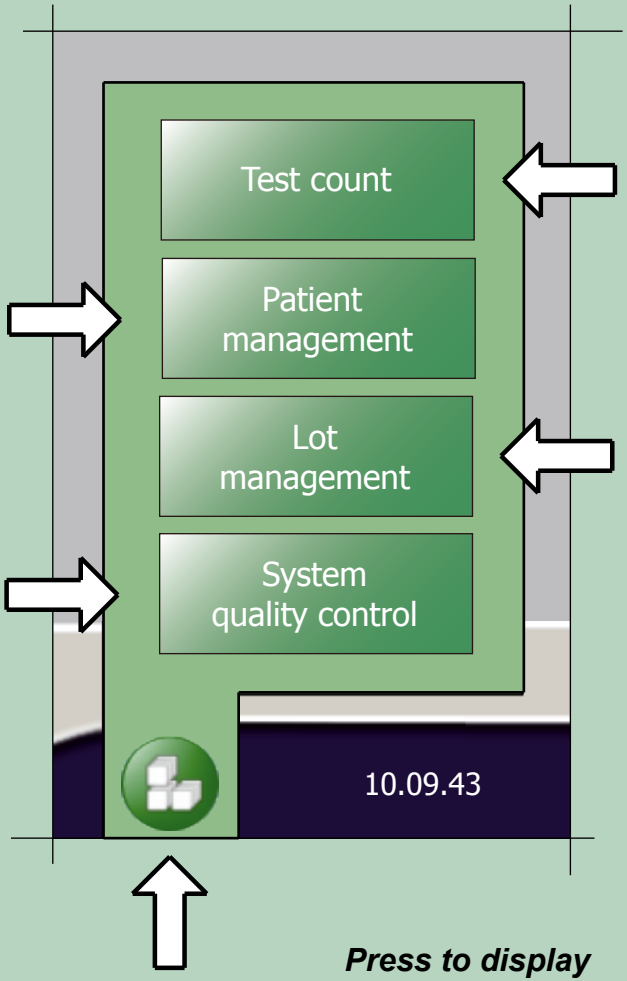
3

To modify a type, select a line item, press **"Edit"**, change the information and press **"OK".**

Work modules

Tests retrieved from "ARCHIVES" for use in the management of patients (OPE.40).

QC results and statistics of single methods; Performance report of the entire system (OPE.46).



Cumulative listing of the number of tests executed for each method programmed (OPE.39).

All functions dealing with the management of calibrator and control lots (OPE.44).

"Access" modules

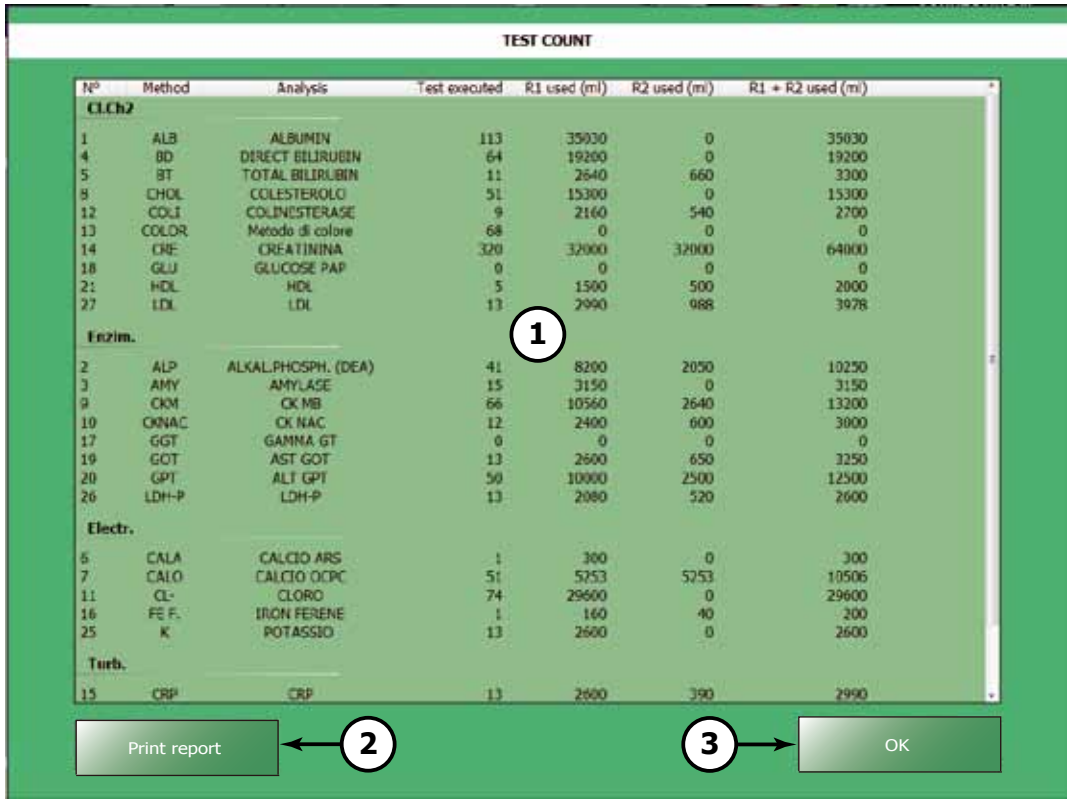
Press to display available special management features

Test count module

This special management feature provides a continually updated record of all testing activities executed including liquid quantities of reagents that have been used.

Test count

Select this module to review the number of tests recorded per method; Print a report of current listings.


TEST COUNT
Nº Method Analysis Test executed R1 used (ml) R2 used (ml) R1 + R2 used (ml)
CLCh2
1 ALB ALBUMIN 113 35030 0 35030
4 BD DIRECT BILIRUBIN 64 19200 0 19200
5 BT TOTAL BILIRUBIN 11 2640 660 3300
8 CHOL COLESTEROLO 51 15300 0 15300
12 COLI COLINESTERASE 9 2160 540 2700
13 COLOR Metodo di colore 68 0 0 0
14 CRE CREATININA 320 32000 32000 64000
18 GLU GLUCOSE PAP 0 0 0 0
21 HDL HDL 5 1500 500 2000
27 LDL LDL 13 2990 988 3978
Enzim.
2 ALP ALKALPHOSPH. (DEA) 41 8200 2050 10250
3 AMY AMYLASE 15 3150 0 3150
9 CKM CK MB 66 10560 2640 13200
10 CKNAC CK NAC 12 2400 600 3000
17 GGT GAMMA GT 0 0 0 0
19 GOT AST GOT 13 2600 650 3250
20 GPT ALT GPT 50 10000 2500 12500
26 LDH-P LDH-P 13 2080 520 2600
Electr.
6 CALA CALCIO ARS 1 300 0 300
7 CALO CALCIO OCPC 51 5253 5253 10506
11 CL- CLORO 74 29600 0 29600
16 FE F. IRON FERENE 1 160 40 200
25 K POTASSIO 13 2600 0 2600
Turb.
15 CRP CRP 13 2600 390 2990
1
Print report
2
3
OK

1
Number of tests counted per method

2
Print a report of tests counted

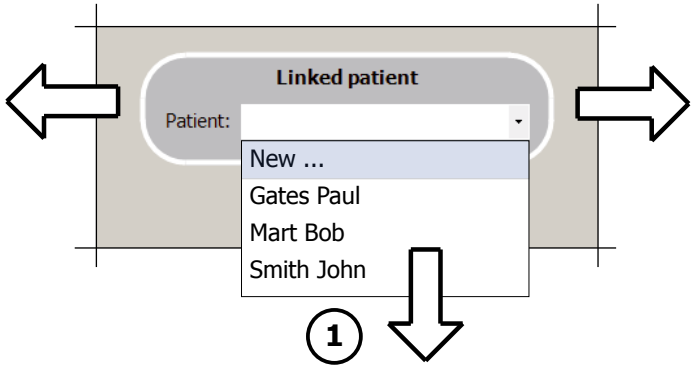
3
Exit "TEST COUNT" module

The "Linked patient" box (lower right corner of the "SAMPLE tab") permits the user to quickly link samples with patients during routine sample creation or editing (OPE.21).

2

If "New ..." in "Linked patient" has been selected this panel will be displayed

Enter the required information and **"Add"** the new patient.

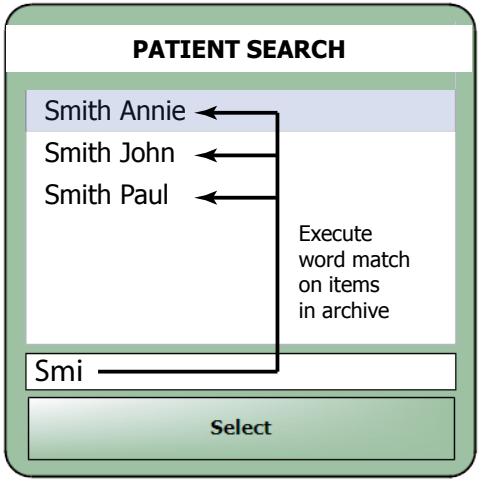


1

A patient selected will be directly linked to the selected sample

3

Type any key indentifying word, (Name, Family name, Type, ID) to initiate a search in the archive



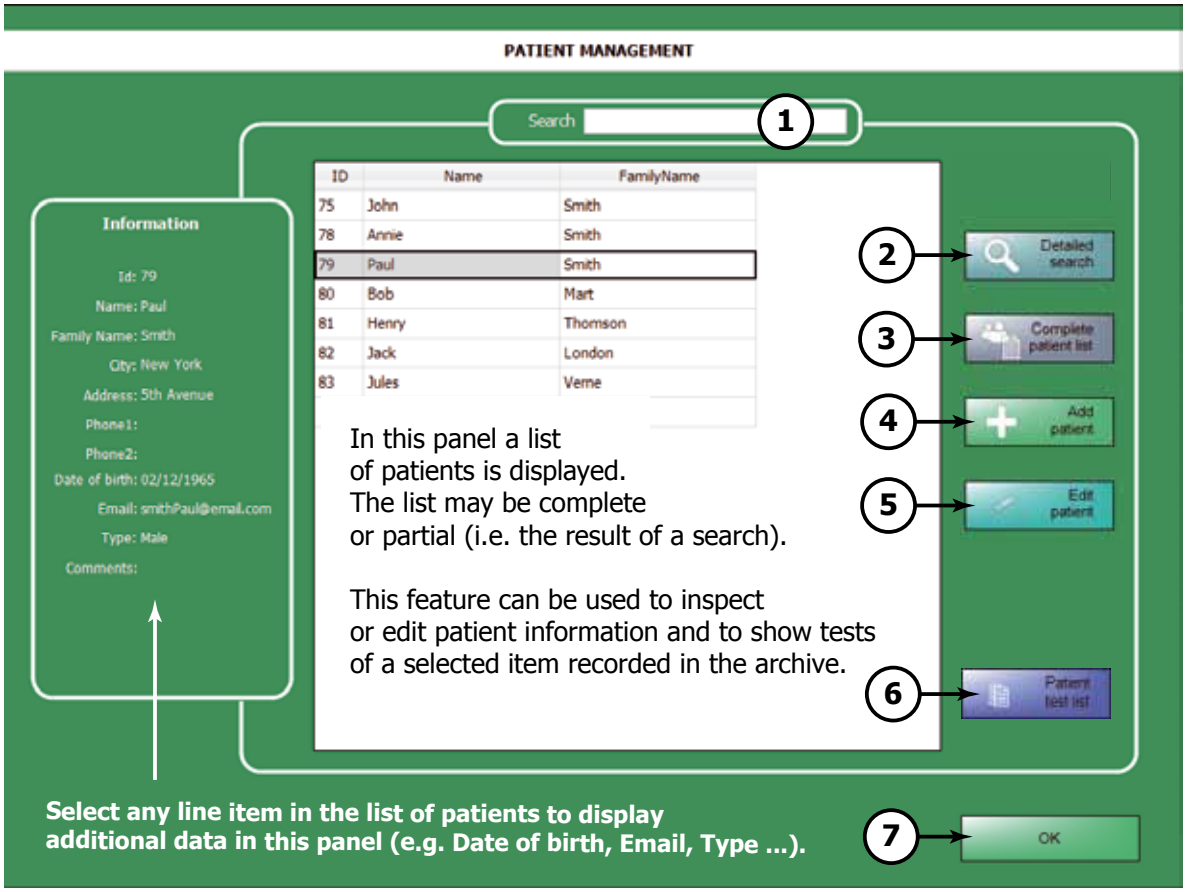
During the test execution, when a test linked to a patient is completed, a new item will be recorded in the archive making it possible to search for old tests executed or to track the progress over time of individual patients.

Patient management module

This module provides information and procedures for the optimum operation and the efficiency of patient management (e.g. list of patients, patient searches, tests organized by date or analysis, stored test features).

Patient management

List patients and search for individual patient records.



(1) Enter **"Key"** indentifying words (i.e. Name, Family name,Type, ID) to search for patients in archive

(2) Access **"Detailed search"** to identify patients by entering key words

(3) Display **"Complete list"** of patients in archive

(4) **"Add"** a new patient to the list

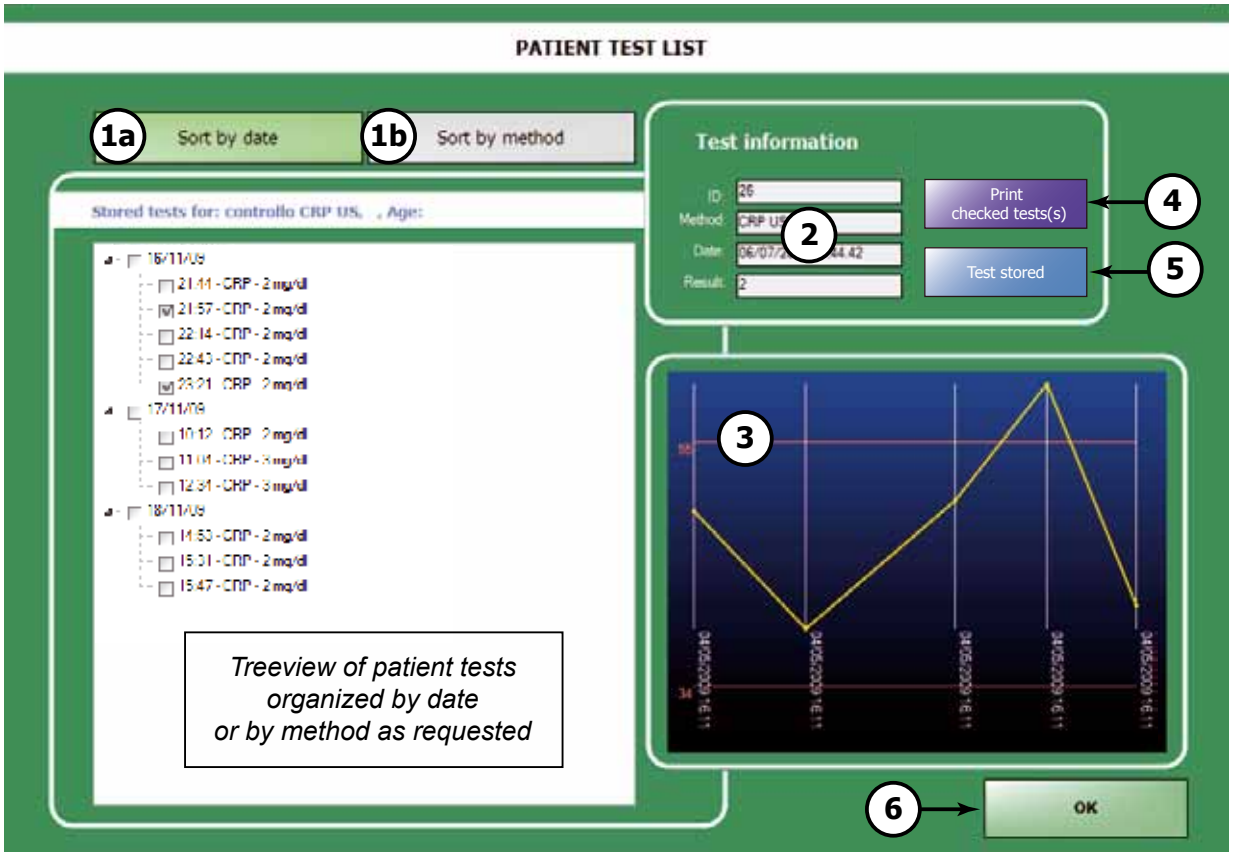
(5) **"Edit"** selected line item

(6) Access **"Patient test list"** panel (OPE.42)

(7) **Exit** "PATIENT MANAGEMENT" module

Patient management module, continued

Access the patient list of tests organized by date or by analysis and print reports.



1a **"Sort tests by date"** of execution

1b **"Sort tests by method"** of analysis

2 **"Test information"** Partial information about the selected test (ID, Method, Date, Result)

3 Graphic showing the evolution of test results over time. Select **"Sort by method"** (1b) and then the method name in the list to plot the graphic

4 **"Print"** a report of the tests previously checked in the list

5 For detailed information about the selected test access the **"Test stored"** form...

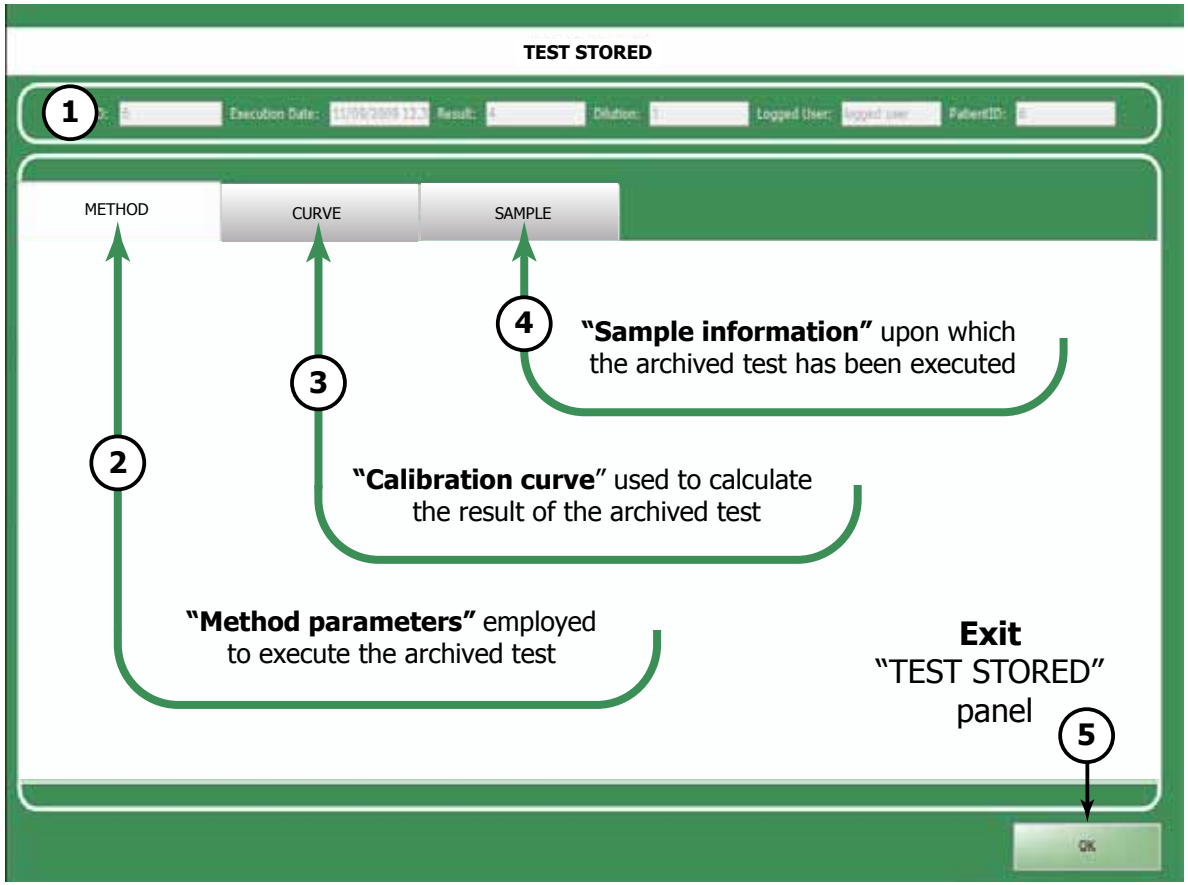
Test stored (next page)

6 **Exit** "PATIENT TEST LIST" panel

The information provided here will allow the operator to retrieve data from past situations to identify previous testing anomalies that may have occurred. Equipped with this knowledge the operator is in a position to apply the work practices that are expected from a modern laboratory (national or international standards may apply).

Test stored

Access a single test showing system status (e.g. method, calibration, sample information) precisely at the moment of execution of that test.



1

"General information" about the test (i.e. Test ID, Date of execution, Result, Dilution, Logged operator, Patient ID)

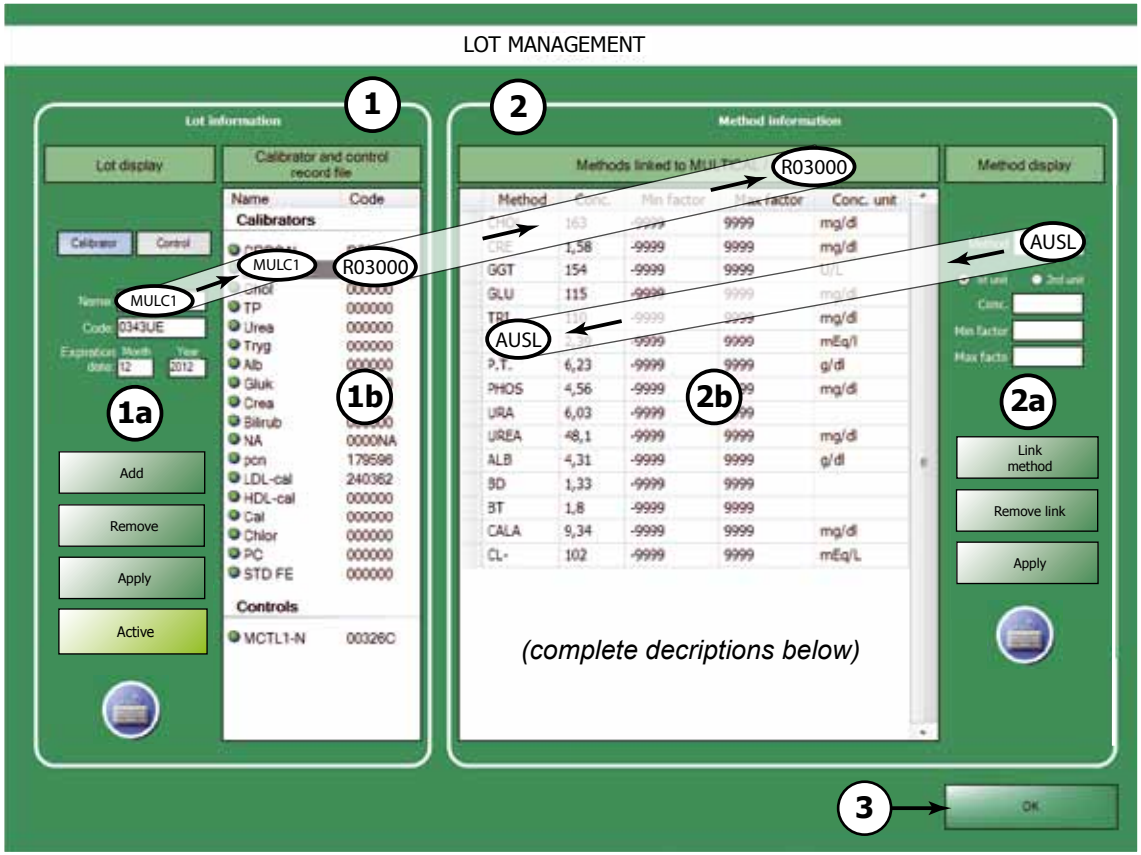
Lot management module

To simplify the information loading and monitoring process,
this module has been designed to manage
the calibrators and control lots in a single database.

Lot management

**Load new lots of calibrators and controls;
Link methods to lots;
Inspect the current listings.**

With this module users can add new lots and specify multiple methods. Each lot can be linked to as many methods as required and once a lot/method linkage has been established it need never be recorded again. Unused lots can be deactivated.



1

This panel deals with all lot functions (e.g. entering, recording, storing)

1a

Enter the name of a new lot, (select calibrator or control) and enter code and date of expiration in text boxes; See additional commands below ...

Add — **"Add"** lot entered to record file

Remove — **"Remove"** lot displayed from record file

Apply — **"Apply"** adjustments made to lot displayed

Active / Stored — **"Activate / Stored"** Indicates the lot status (active or stored); Click to change (lots with same name cannot be activated at the same time)

1b

List of lots currently recorded

2

This panel deals with method selection and the linkage of methods to lots

2a

Select the method required for linkage from choices in the "list ▾" provided; See additional commands below ...

Link method — **"Link"** method chosen to the lot selected in panel 1a

Remove link — **"Remove link"** selected

Apply — **"Apply"** adjustments made to method displayed

2b

List of all methods currently linked with the selected lot (name and code indicated)

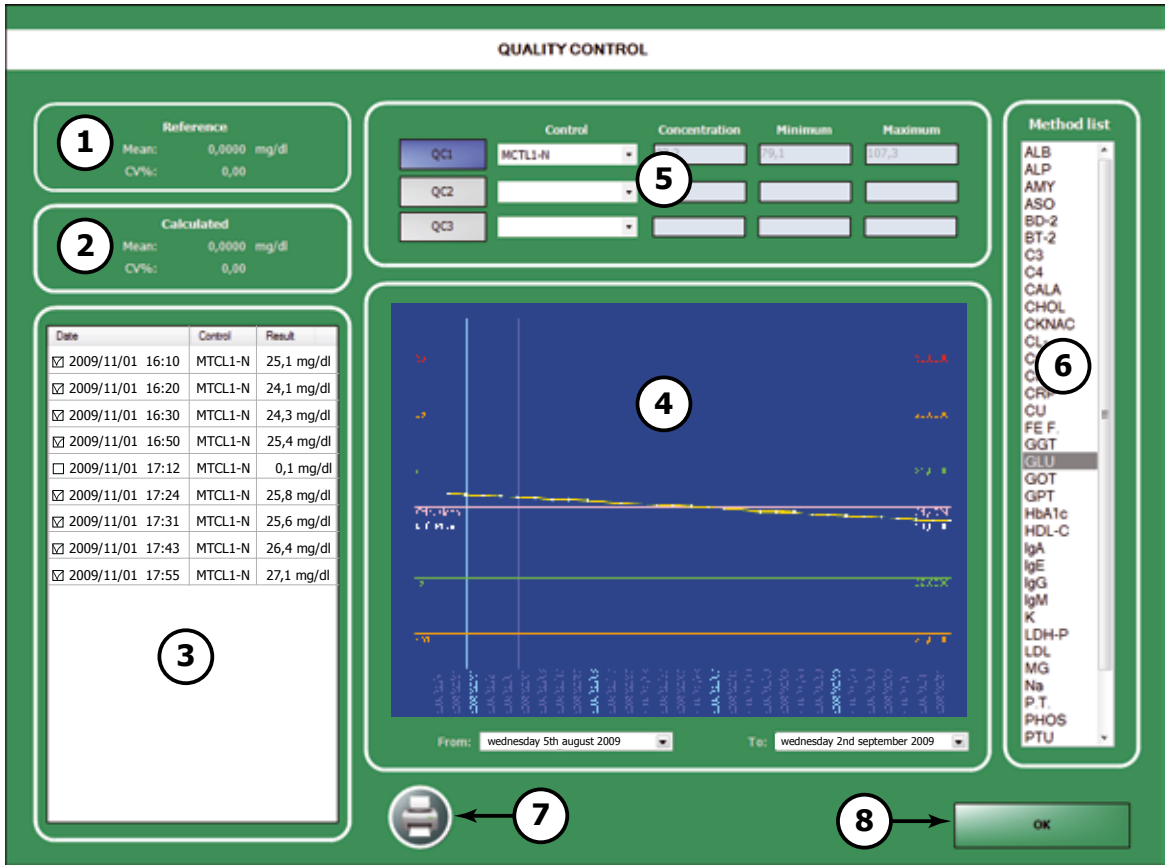
3

Exit "LOT MANAGEMENT" module

Quality control management module

QC

This module has been designed to control the quality of the system by monitoring the QC results of methods and extracting information regarding the accuracy of the instrument.



System quality control

Assigns controls to methods (up to three conrols per method); Provides a Levey-Jennings graphic of all QC results executed over time; Determines accuracy level of the instrument; Prints a report of quality controls.

1

"Reference" values for mean and CV% taken from control lot data (OPE.44)

2

"Calculated" values for mean and CV% using all items checked in test results list (Item 3)

4

Levey-Jennings graphic of QC results with dated reference lines

It is possible to select the period of control evaluation using the **"From"** and **"To"** date selections

3

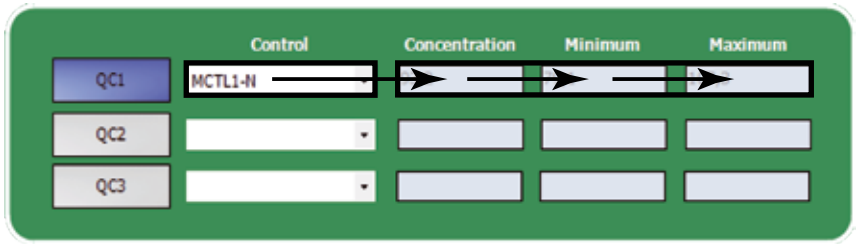
List of tests executed in the selected period (see item 4) for the selected method and control

Any items that remain unchecked will be excluded from the values calculated and also from the graphic chart

If more than one QC test has been executed per day, only the final test will be checked

5

Access "list ▼" and select a "Control" for each of the three QC operations to be used



6

List of methods available

7

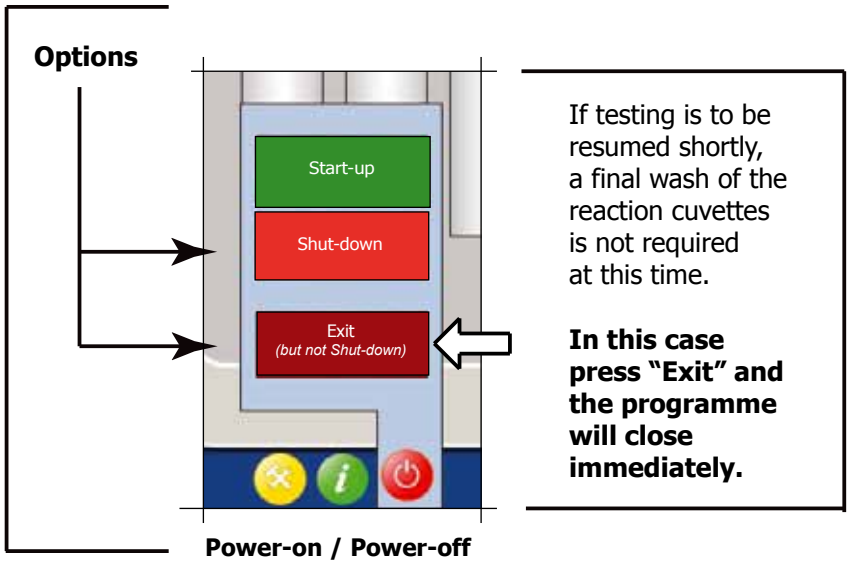
Print daily report of the quality control selected for current method

8

Exit "QUALITY CONTROL" module

Power-off / Shut-down / Switch-off

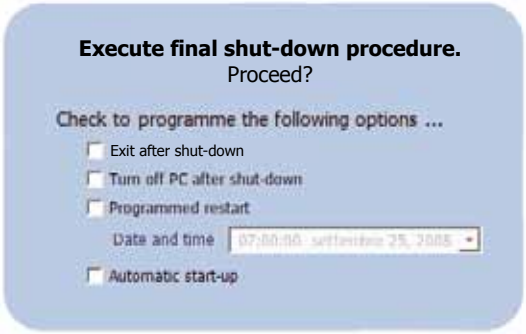
1 To begin **closing** procedures,
first click the **"Power-off"** button
to access the options required.



If testing is to be resumed shortly, a final wash of the reaction cuvettes is not required at this time.

In this case press "Exit" and the programme will close immediately.

2 To continue closing procedures,
select the **"Shut-down"** option
to access the final shut-down procedure.



Shut-down options

Check automatic actions to be run after shut-down:
i) exit software
ii) turn off PC
iii) restart when required (e.g. next morning)
iv) automatic start-up following restart

3 Switch off the **PC**
and the **touch screen monitor**.

4 Switch off the analyzer.

Switch for reagent refrigeration plate ⇨

⇦ Main power switch

If for any reason the analyzer is to be switched off, but the reagent trays are to remain on-board, be sure to leave the refrigeration plate on.

If "Programmed restart" has been checked during "Shut-down" do not turn off the main power switch and the instrument will hybernate until the selected "Date and time".

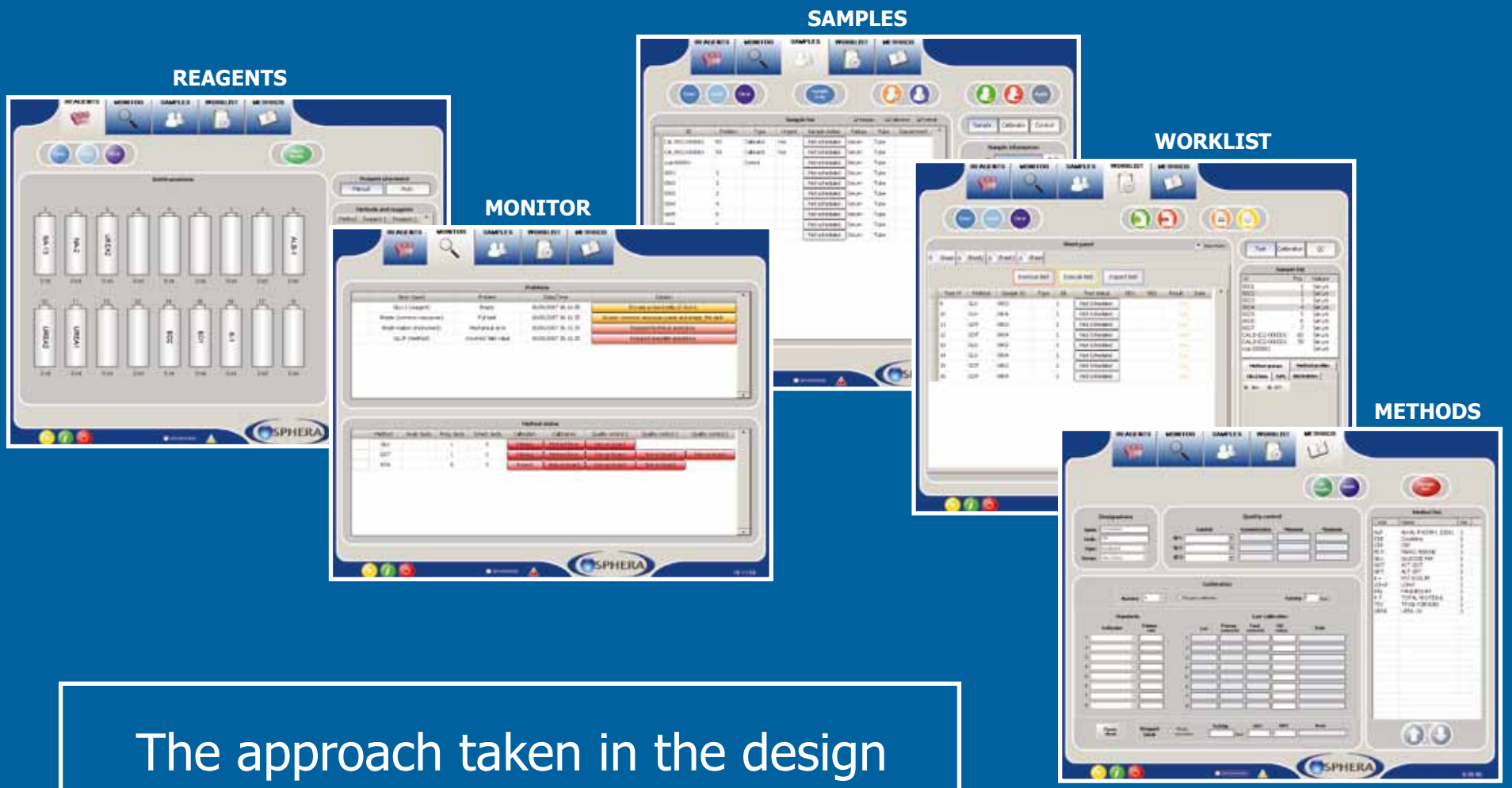
ADDITIONAL INFORMATION CONCERNING "SHUT-DOWN"

Each day, following the completion of the work scheduled, a Shut-down procedure is required to initiate the cleaning of the reaction cuvettes (before switching off the analyzer).

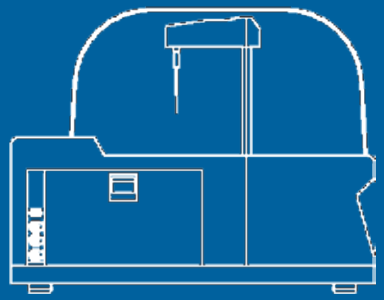
If this procedure is neglected any test residue remaining may damage the cuvette walls. This will reduce testing accuracy and possibly require earlier replacement of cuvettes.

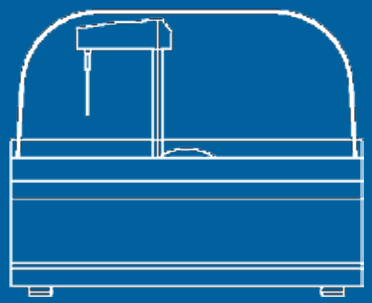
Notes

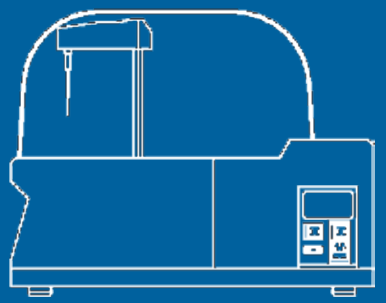
Edif Instruments would welcome receiving any comments or feedback from the operator so that over time improvements can be made.



The approach taken in the design of Edif products and the Edif line of analyzers is simplicity itself.







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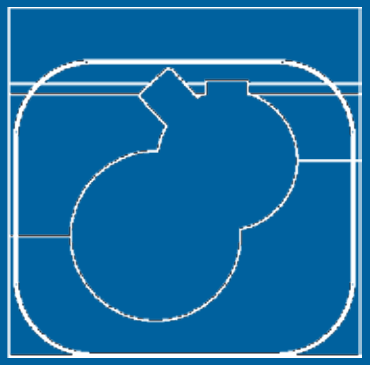

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